

Low Dose Naltrexone

Novel uses for a licenced medication

Dr. Phil Boyle,
New Orleans, August 2013

Faculty Disclosure

Doctor Phil Boyle, MD

Dr. Boyle has listed no financial interest/arrangement that would be considered a conflict of interest.



Publications

- PubMed search “[Low Dose Naltrexone](#)” – 73 results
 - Pain Relief
 - Opioid, Alcohol and smoking cessation
 - Fibromyalgia
 - Crohn’s – Adults and children
 - Systemic Sclerosis
 - Cancer Treatment
 - Multiple sclerosis

Naltrexone Hydrochloride – Nalorex

- Growing number of novel uses for this licenced drug
- Nothing published on “Low dose Naltrexone” for Infertility, Miscarriage, PMS or Pregnancy
- But.....High dose naltrexone....There is

<http://www.medicines.ie/medicine/1664/SPC/Nalorex/>

Naltrexone Hydrochloride – Nalorex

This is a licenced drug

- 50mg – 150mg per dose
- First synthesised in 1960s
- Licenced USA 1985 – Ireland 1991
- Adjunctive treatment of opioid dependence...and now alcohol dependence (unlicenced)
- Competitive inhibition of opioid receptors in both the central and peripheral nervous system

Naltrexone Hydrochloride – Nalorex

Special warnings and precautions for use

- Adverse reaction with opioids – severe – ensure no opioid use
- Confirm normal kidney and liver function
- Some elderly patients on 300mg naltrexone develop abnormal liver function tests
- No evidence of toxicity in volunteers receiving 800 mg/day for seven days
- Prolonged use at 50mg is acceptable.....duration of treatment is not limited

Quantity matters.....

One glass of wine



Quantity matters.....

One glass of wine



One glass of wine



Naltrexone Hydrochloride – Nalorex

Clinical experience using low dose naltrexone 4.5mg since 2004

- Have not seen abnormal liver function
- It is not necessary to monitor liver function with low dose naltrexone
- BUT – never mix it with opioids – vomiting for hours – severe!

Naltrexone Hydrochloride – Nalorex

Animal studies do not suggest a teratogenic effect, but there is no experience of use during human pregnancy. The drug should only be used in pregnancy or lactation if considered essential by the physician.

Naltrexone has few, if any, intrinsic actions besides its opioid blocking properties.

Naltrexone Hydrochloride – Nalorex

Absorbtion – peak levels after 1 hour

Half Life of 4 hours

The duration of action of a drug is known as its half life. This is the period of time required for the concentration or amount of drug in the body to be reduced by one-half.

Naltrexone, Infertility

PubMed search – 10 publications

We will look at 4 interesting papers.....

Steroids 2012

Medical management of metabolic dysfunction in PCOS.

“Naltrexone reduces appetite and modulates insulin release; its use in PCOS may reduce hyperinsulinemia.”

Duleba AJ. Reproductive Endocrinology and Infertility, Univ. of California

<http://www.ncbi.nlm.nih.gov/pubmed/22182833>

Journal of Endocrinological Investigation

- **Naltrexone effect on pulsatile GnRH therapy for ovulation induction in polycystic ovary syndrome: a pilot prospective study.**

Fulghesu AM et al. Sacred Heart University, Rome, Italy - 2001

Naltrexone 50mg with pulsatile GnRH co-treatment is able to improve the ovarian responsiveness to ovulation induction in **obese PCOS patients** when compared to pulsatile GnRH alone.

This action seems to be related to a decrease of insulin secretion.

<http://www.ncbi.nlm.nih.gov/pubmed/11508781>

Human Reproduction 1997

Successful induction of ovulation in normogonadotrophic clomiphene resistant anovulatory women by combined naltrexone and clomiphene citrate treatment.

Roozenburg BJ, van Dessel HJ, Evers JL, Bots RS.

- 22 patients with clomiphene resistant normogonadotrophic anovulation treated with naltrexone alone or in combination with clomid.
- 19 patients ovulation and resumption of a regular menstrual cycle
- 12 out of 19 a singleton pregnancy was observed.....2 of these miscarried

<http://humrep.oxfordjournals.org/content/12/8/1720.full.pdf+html>

Human Reproduction 1997

- All women resistant to clomiphene 150mg daily x 5 days – for 2 cycles
- Treated with naltrexone 25 mg twice daily
- Goal - complete opioid blockade – to treat hypothalamic inhibition of GNRH from excessively high endorphins
- 18 required clomiphene 100mg daily for 5 days
- Continued treatment for 6 cycles

Human Reproduction 1993

Treatment with naltrexone in hypothalamic ovarian failure: induction of ovulation and pregnancy.

Wildt L, Leyendecker G, Sir-Petermann T, Waibel-Treber S.

University of Erlangen, Germany

66 women

- various grades of hypothalamic ovarian failure
- Normalisation of cycle in 49 women – 18 pregnancies

High Dose Naltrexone

- This appears to be a different mechanism of action compared to **LOW DOSE NALTREXONE**.....worth considering for excessive opioid production (Endorphins, Enkephalins.....)
 - Clomiphene resistant
 - PCOD
 - Obese and very thin – extremes of weight
 - Highly stressed

Naltrexone, Infertility

Possible Mechanisms of action of High Dose Naltrexone

- Reduces insulin resistance
- Improves GNRH pulse frequency
 - Possibly by altering opioids where there is “an inappropriate increase in opioid tone”

Naltrexone, Pregnancy

PubMed search – [138 Publications](#)

For doses up to 150mg Naltrexone has been proven safe for most adults except pregnant or nursing women.....and probably those with acute hepatitis;

Naltrexone, PMS

PubMed search – 1 publication

Clinical trial of naltrexone in premenstrual syndrome.

Chuong CJ, Coulam CB, Bergstralh EJ, O'Fallon WM, Steinmetz GI.

Obstet Gynecol. 1988 Sep;72(3 Pt 1):332-6.

.....

Department of Obstetrics and Gynecology, Mayo Clinic, Rochester, Minnesota.

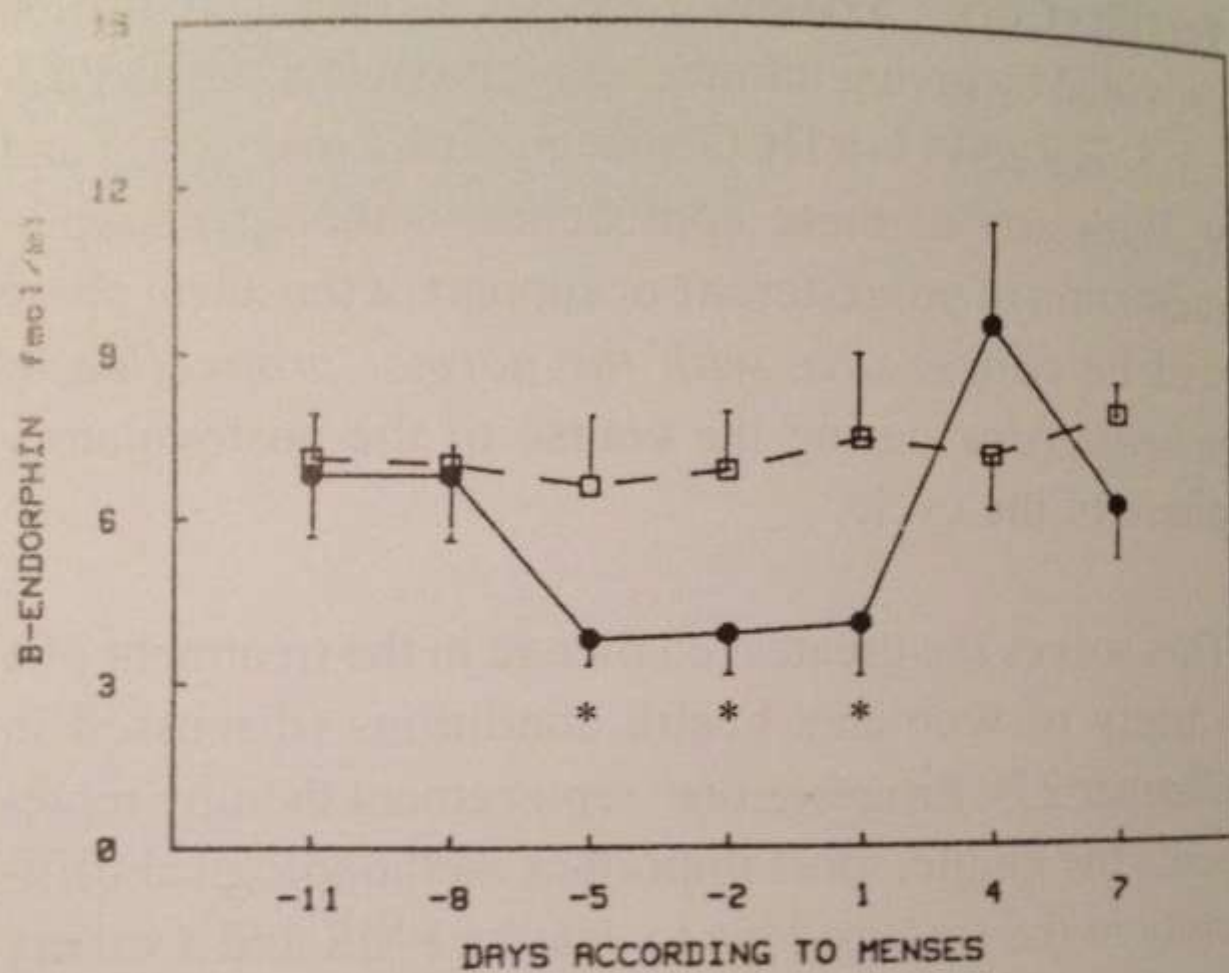


Figure 29-8: Plasma β -endorphin changes (mean \pm SE) in the perimenstrual period in PMS patients (solid line) and controls (dashed line). * $p < .05$ between groups (From: Facchinetti F, Martignoni E, Petraglia F, Sances MG, Nappi G, Genazzani AR: Premenstrual Fall of β -endorphin in Patients with Premenstrual Syndrome. *Fertil Steril* 47:570-573, 1987).

Naltrexone, PMS

20 women - double-blind, placebo-controlled, crossover study

Naltrexone 50mg – days 9-18 of cycle – to test inhibition of opiate withdrawal

Menstrual Distress Questionnaire (\$100 for 50 copies)

The mean scores dropped 28 points on naltrexone ($P = .016$).

Naltrexone alleviates many PMS symptoms and may be an effective treatment for this syndrome.....but Nausea, decreased appetite and dizziness

Naltrexone – opioid receptor antagonist

Endogenous Opioid Peptides

- Endorphins
- Enkephalins
- Dynorphins

Naltrexone blocks all of the receptors

Receptors CNS and PNS

- Epsilon (Endorphins)
- Delta (Enkephalins)
- Kappa (Dynorphins)
- Mu (Morphine)
- Sigma

Naltrexone – mechanism of action

Naltrexone – antagonism and rebound

Consider Letrozole –

1. Ovulation Induction and subsequent increase in oestrogen production
 - Letrozole – 20mg day 3 one day of cycle – rebound increase in oestrogen
2. Suppression of oestrogen production through aromatase inhibition
 - Letrozole 2.5mg every day continuously - a drop in oestrogen levels

The same medication has a profoundly different effect depending on how it is given

Naltrexone – antagonism and rebound

Consider Naltrexone –

1. Hoped to increase in endorphin production

- Naltrexone 25mg bd **for 10 days**- (day 9-18) – rebound increase in beta endorphins

2. Suppression of endorphin production through

- Naltrexone 25mg bd **every day continuously** - a drop in endorphin levels

The same medication has a profoundly different effect depending on how it is given

Naltrexone, PMS

Now Consider Low Dose Naltrexone 3-4.5mg nightly

- Naltrexone has a daily circadian rhythm
- Briefly and temporarily blocking endorphin receptors at night triggers a rebound stimulation of endorphins the following day
- x 3-4 fold increase in Beta Endorphin Levels – B. Bihari
- x 12-15 fold increase in enkephalin levels – J. Smith
- Vastly superior to naltrexone 25mg BD for 10 days (9-18) of cycle

Naltrexone, PMS

The International Institute for Restorative Reproductive Medicine

www.iirrm.org – We intend to do a clinical trial with LDN 3-4.5mg nightly

Interested doctors – please contact us !

- Clinical experience in treating PMS is 80% response
- Many say – I have my life back – I am me again!!

Low Dose Naltrexone

New uses of an old drug see www.lowdosenaltrexone.org

A proposed different mechanism of action

Naltrexone temporarily and briefly blocks opioid receptors, triggering a rebound increase in endogenous opioid production

Improving endogenous endorphins has multiple beneficial effects for endorphin deficient patients

Current concepts of beta-endorphin physiology in female reproductive dysfunction

Elevated or high levels of **beta-endorphin** have been associated with exercise-associated amenorrhea, stress-associated amenorrhea, and polycystic ovarian syndrome.(High Dose Naltrexone 25mg BD) PPVI, Omaha.

Depressed or low levels of **beta-endorphin** have been associated with PMS and menopause, (Endometriosis – Hilgers)(Low Dose Naltrexone 3-4.5mg nightly)

Galway, Ireland

Fertility and Sterility 1990. Seifer DB et al, Yale University School of Medicine

<http://www.ncbi.nlm.nih.gov/pubmed/2226908>

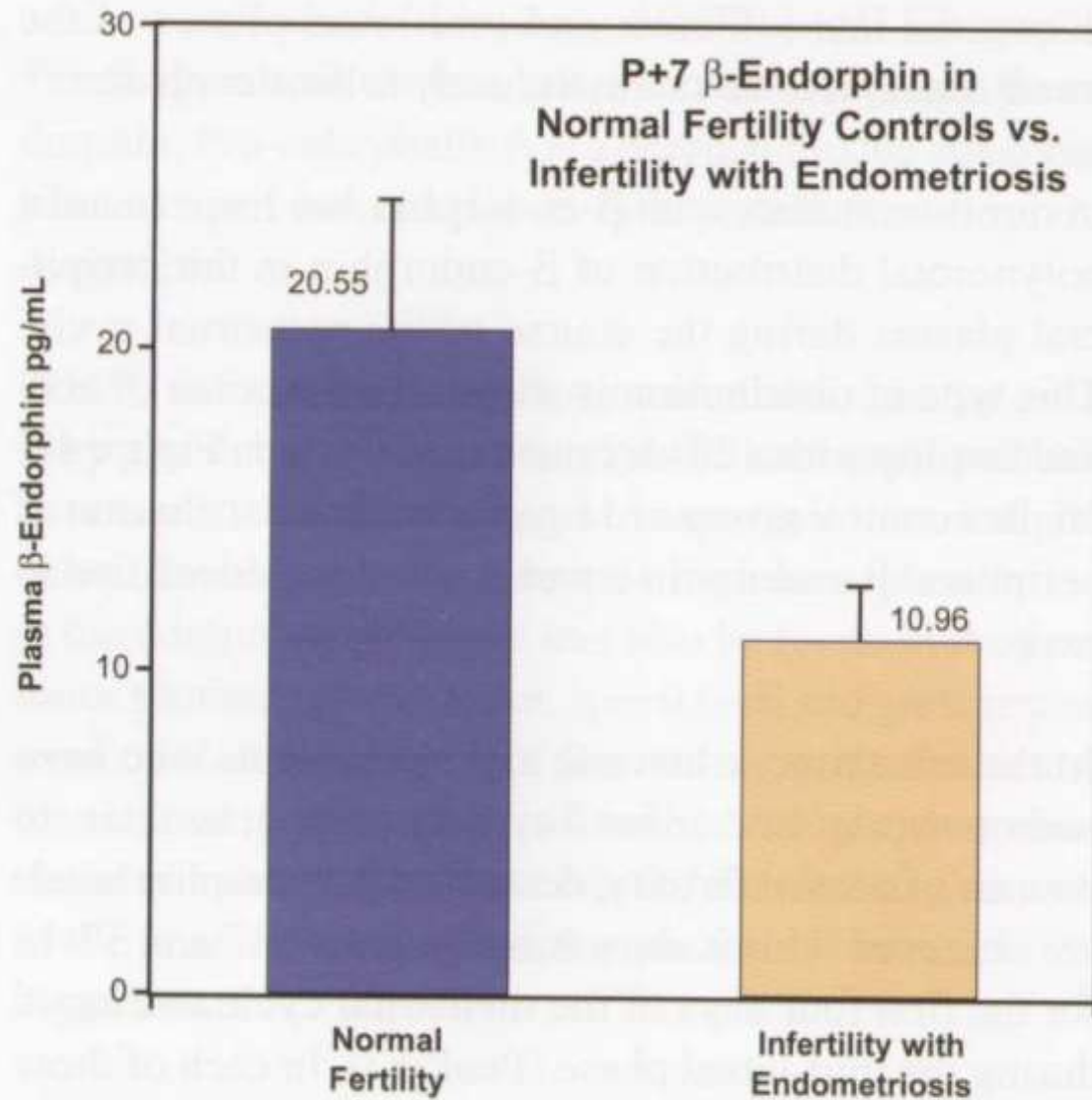


Figure 41-18: Plasma beta-endorphin levels during the luteal phase (Peak +7) in women of normal fertility versus those with infertility due to endometriosis ($p < .01$) (From: Pope Paul VI Institute research, 2004).

Table 43-7: Incidence of Endometriosis in Patients with PCOD¹ (N=55)

	n	%
With endometriosis	28	50.9
No endometriosis	27	49.1

1. As determined at the time of laparoscopy.

From: Pope Paul VI Institute research. 2004.

Current concepts of beta-endorphin physiology in female reproductive dysfunction

Not a case ofEither /Or

But rather Both / And

We should consider Naltrexone in both low and high dose

Endorphin Stimulation

- Immune modifying effect
 - Intestinal
 - Local effects
 - Central effects
- Mood enhancement
- Increased energy levels

Endorphin Stimulation



- Immune modifying effect

- **Local effects** – Reduces pro-inflammatory cytokines

Interleukin (2,6,12), TNF (Tumor Necrosis Factor) alpha, Gamma Interferon

- Cause inflammation from wbc and macrophages

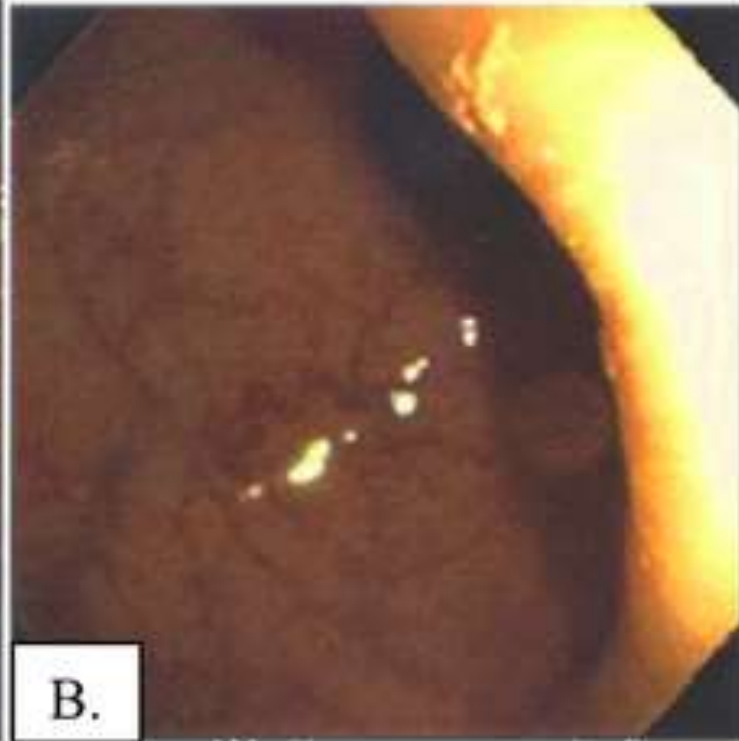
Naltrexone influences mu, kappa and delta receptors locally

Central effect increases endogenous enkephalins (Met-enkephalin) centrally to heal the bowel.

Professor Jill Smith – Am J. Gastro 2007.



A.



B.

Endoscopic Improvement in Crohn's Colitis with Naltrexone

Figure A: Shown is the rectum of a subject with active Crohn's Disease before starting therapy with naltrexone 4.5 mg/day. The mucosa is ulcerated, edematous, and inflamed.

Figure B: Shows the same area of the rectum in the same patient four weeks after naltrexone therapy. The lining is now healed, ulcers resolved, and the mucosa is healthy.

Professor Jill Smith – Am J. Gastro 2007.

Effect of LDN 4.5mg a day – treated 17 patients

- 89% improvement in Crohns Disease
- 67% in remission

- 70% -previous failed TNF alpha inhibitor – Infliximab (Remicade)

Professor Jill Smith – Am J. Gastro 2007.

Effect of LDN 4.5mg a day – treated 17 patients

- 89% improvement in Crohns Disease
- 67% in remission
- 70% -previous failed TNF alpha inhibitor treatment –
- Infliximab (Remicade) \$ 5,000⁺ per infusion - repeatedly for Crohn's.
- LDN is \$ 30-50 per month!

Probably Placebo!



You need a Randomized placebo-controlled trial.

Naltrexone promotes mucosal healing in active Crohn's disease: 2011

Randomized placebo-controlled trial.

[Digestive Diseases and sciences 2011](#)

Smith JP, Bingaman SI, Ruggiero F, Mauger DT, Mukherjee A, McGovern CO, Zagon IS.

Department of Medicine, The Pennsylvania State University, College of Medicine, GI Medicine H-045, 500 University Drive, Hershey, PA 17033, USA.

jsmith2@psu.edu

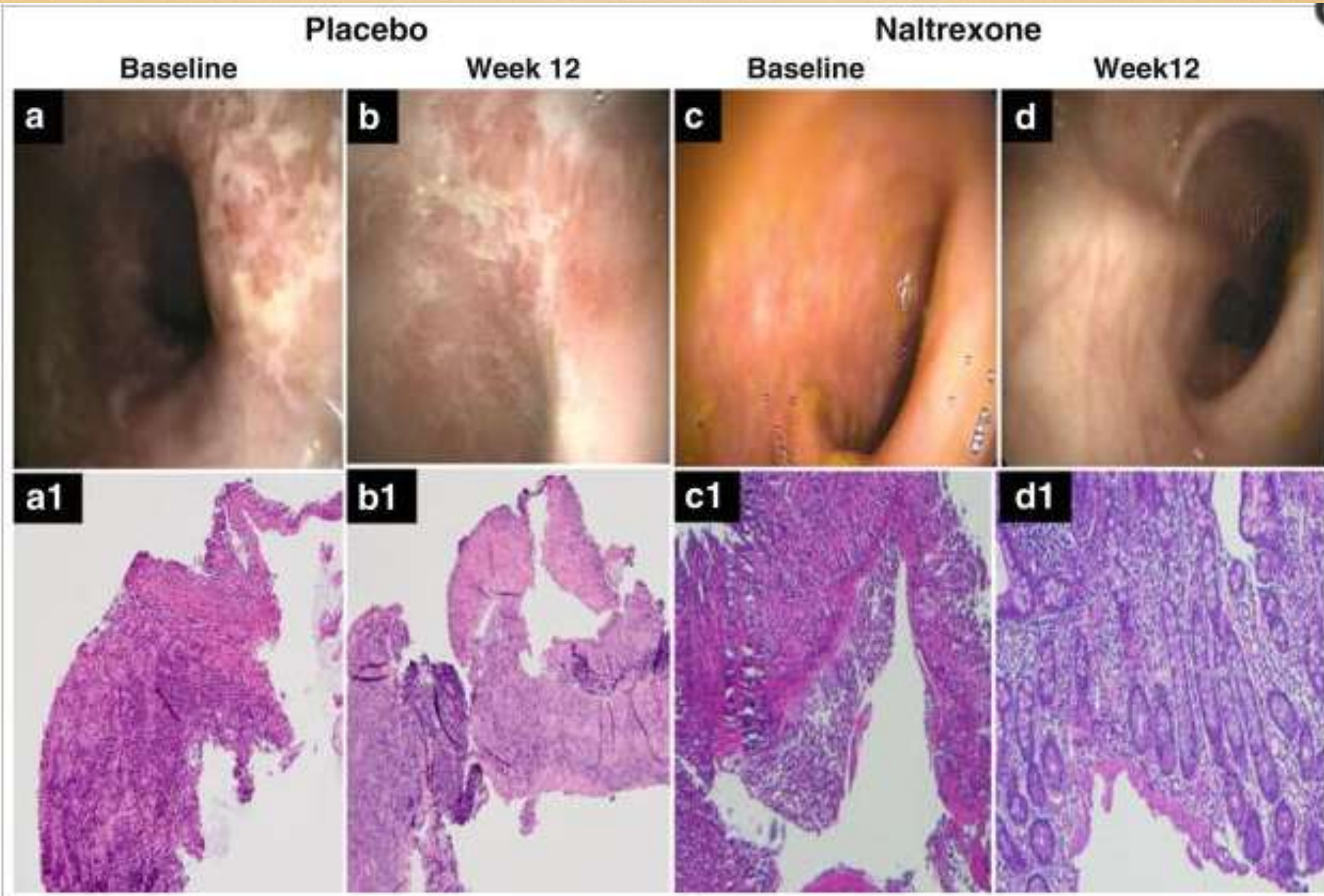
Professor Jill Smith

Digestive Diseases and sciences 2011

Effect of LDN 4.5mg a day – treated 40 patients for 12 weeks

- 88% Clinical response rate compared to 40% in Placebo group (P = 0.009)
- 78% endoscopic response compared to 28% in placebo group (P=0.008)
- 33% remission compared to 6% remission in placebo group

- Naltrexone improves clinical and inflammatory activity of subjects with moderate to severe Crohn's disease compared to placebo-treated controls.



Naltrexone promotes mucosal healing in active Crohn's disease: 2011

Randomized placebo-controlled trial.

Digestive Diseases and sciences 2011 Impact factor 2012 2.260

American Journal of Gastroenterology - Impact factor 2012 7.553

New England Journal of Medicine - Impact factor 2012 51.658

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3381945/>

Probably Advertising Revenue



You need an expensive patented drug to publish your data!

Editor NEJM Forced to Resign in Dispute with the Medical Journal

July 27, 1999

Dr. Kassirer declined to provide specifics of the dispute beyond saying it involved sharp differences in "administrative and publishing issues."

.....other editors said the dispute reflects tensions generated as the society seeks to generate more revenues to expand its influence in an increasingly competitive and political world of health care.

Clinical experience with LDN

- Started to prescribe it in 2004

Low Dose Naltrexone



LDN – plays an important part

- “NaProTechnology - A Multi-factorial approach to the chronic problem of Infertility” - P Boyle, J Stanford

<http://www.fertilitycare.net/documents/NPTMultifactorialApproach.pdf>

- Paper from Kaunas, Lithuania June 2011

Possible Diagnoses from NaProTechnology Evaluation

Hormonal	Ultrasound	Surgical	Other
Low Progesterone	Immature follicle	Endometriosis	Limited (hostile) Mucus
Low Oestradiol	Partial rupture	Pelvic Adhesions	Adrenal Fatigue
Poor Follicular Function	Luteinised unruptured follicle	Blocked Fallopian Tubes	Chronic Endometritis
Corpus Luteum Insufficiency	Delayed Rupture	Hydrosalpinx	Endorphin Deficiency
Polycystic Ovaries	Afollicularism	Fibroid	Food Intolerance
Reduced ovarian reserve	Absent Cumulus Oopherous	Polyp	Nutritional Deficiency
Hypothyroidism		Uterine Septum	Immune dysfunction

Fig. 3

LDN – plays an important part



Low Dose Naltrexone

Clinical Experience since 2004

- LDN is used to treat Clinical Endorphin Deficiency
- About 50% of fertility patients
- Safe to continue during pregnancy and breastfeeding

Clinical Endorphin Deficiency

1. PMS
2. Polycystic ovaries or Endometriosis
3. TEBB
4. Fatigue 2 or more of these
5. Low Mood
6. Anxiety
7. Sleep
8. Family History of Autoimmunity

Clinical Endorphin Deficiency

- Available from brochure
 - <http://fertilitycare.net/documents/LDNInfoAug13aa.pdf>

Side Effects

1. Vivid Dreams
2. Sleep Disturbance
3. Nausea *for about 2 weeks*
4. Headache
5. Dry Mouth *over 95% acceptable*

Drug Interactions

1. Morphine
 2. Codeine
 3. Alcohol
- Safe to combine with steroids
 - Discontinue 2 days before surgery and resume after stopping pain relief

No longer an Experimental Treatment

- It is a licensed drug but at a much higher dose (50mg) for a different indication – drug addiction
- A growing number publications at LDN Website
 - MS, Crohn's and fibromyalgia
- A proven potent immune modifying treatment through a double blinded randomized placebo controlled trial 2011

Low Dose Naltrexone

Dosage

- 3mg nightly
- or
- 4.5mg nightly

Low Dose Naltrexone

- Needs to be specially compounded as
- Fast release preparation
 - Not lactose or calcium carbonate filler
 - Preferably microcrystalline filler (avicel)
- Suppliers listed
 - www.lowdosenaltrexone.org

Clinical Experience

1. Case C – 3 previous failed IVF cycles
2. Six recurrent miscarriages

Case C

- Gravida 1 (with IVF), Para 0, 5 Years of primary infertility
- Female age 38, Male age 38
- Mild Endometriosis
- 12 previous cycles of clomid
- 3 attempts at IUI
- 3 previous failed IVF

Case C – NPT Diagnoses

- Endometriosis
- Oligoasthenozoospermia
- *Clinical endorphin deficiency*
- Low progesterone and oestradiol – combined poor follicle function and corpus luteum insufficiency *Obvious from Chart*
- Food Intolerance to eggs

P

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Pre-menstrual Spotting with low progesterone levels

USE THESE SIGNS: P = PEAK • 1,2,3 = FERTILE DAYS FOLLOWING PEAK • I = INTERCOURSE BE = BREAST SELF-EXAM

Case C – NPT Treatments

- Clinical endorphin deficiency - **significant**
 - Naltrexone 4.5mg nightly
- Food Intolerance to eggs
 - Change in diet

Case C – NPT Treatments

- Endometriosis
 - Laparoscopy and diathermy June 2008
- Oligoasthenozoospermia
 - CoEnzyme Q10 200mg daily
 - Tamoxifen 20mg daily
 - FertilityPlus for men
 - Lifestyle – (cigarettes, alcohol, caffeine, stress)

Case C – NPT Treatments

- Low progesterone and oestradiol – combined poor follicle function and corpus luteum insufficiency
 - Clomiphene 150mg daily x 3 days, starting on day 3 of the cycle with HCG 5000 iu mid cycle to facilitate follicle rupture and HCG 2,500 iu on days 3, 5 and 7 after ovulation

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USE THESE SIGNS: P = PEAK • 1.2.3 = FERTILE DAYS FOLLOWING PEAK • I = INTERCOURSE BE = BREAST SELF-EXAM

P = 41
E = 49

P = 68.5
E = 435

P = 101
E = 425

MCS = $E_1 + E_2 + E_3 + 10 = 6$
 $60 = 20 + 20 + 20$

PP = 13
P =
E =

D.D. 14 12 N3 x 24 / p 5 - 22 / p 7 - 12

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DESCRIPTION	K	H	H	L	L	L	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	
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DESCRIPTION	K	H	H	L	L	L	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	
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DESCRIPTION	K	H	H	L	L	L	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE
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Date	10/1	10/2	10/3	10/4	10/5	10/6	10/7	10/8	10/9	10/10	10/11	10/12	10/13	10/14	10/15	10/16	10/17	10/18	10/19	10/20	10/21	10/22	10/23	10/24	10/25	10/26	10/27	10/28	10/29	10/30	10/31	11/1	11/2	11/3	11/4	11/5		
DESCRIPTION	K	H	H	L	L	L	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE
STAMP	[Red]	[Red]	[Red]	[Red]	[Red]	[Red]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]
Date	10/1	10/2	10/3	10/4	10/5	10/6	10/7	10/8	10/9	10/10	10/11	10/12	10/13	10/14	10/15	10/16	10/17	10/18	10/19	10/20	10/21	10/22	10/23	10/24	10/25	10/26	10/27	10/28	10/29	10/30	10/31	11/1	11/2	11/3	11/4	11/5		
DESCRIPTION	K	H	H	L	L	L	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE

Laparoscopy

USE THESE SIGNS: P = PEAK • 1.2.3 = FERTILE DAYS FOLLOWING PEAK • I = INTERCOURSE BE = BREAST SELF-EXAM

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35			
STAMP	[Red]	[Red]	[Red]	[Red]	[Red]	[Red]	[Red]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	
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DESCRIPTION	K	H	H	L	L	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	
STAMP	[Red]	[Red]	[Red]	[Red]	[Red]	[Red]	[Red]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	
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Date	10/20	10/21	10/22	10/23	10/24	10/25	10/26	10/27	10/28	10/29	10/30	10/31	11/1	11/2	11/3	11/4	11/5	11/6	11/7	11/8	11/9	11/10	11/11	11/12	11/13	11/14	11/15	11/16	11/17	11/18	11/19	11/20	11/21	11/22	11/23	11/24	11/25	
DESCRIPTION	K	H	H	L	L	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE
STAMP	[Red]	[Red]	[Red]	[Red]	[Red]	[Red]	[Red]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]
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STAMP	[Red]	[Red]	[Red]	[Red]	[Red]	[Red]	[Red]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]	[Green]
Date	10/20	10/21	10/22	10/23	10/24	10/25	10/26	10/27	10/28	10/29	10/30	10/31	11/1	11/2	11/3	11/4	11/5	11/6	11/7	11/8	11/9	11/10	11/11	11/12	11/13	11/14	11/15	11/16	11/17	11/18	11/19	11/20	11/21	11/22	11/23	11/24	11/25	
DESCRIPTION	K	H	H	L	L	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE	BE

Laparoscopy

Positive Test!

USE THESE SIGNS: P = PEAK • 1.2.3 = FERTILE DAYS FOLLOWING PEAK • I = INTERCOURSE BE = BREAST SELF-EXAM

Case C – NPT Pregnancy Treatments

- Positive pregnancy test in September 2008
- Cyclogest 400mg pv nocte until 14 weeks
- Naltrexone 4.5mg nocte until 38 weeks



Case C – NPT Pregnancy outcome

- They had a healthy baby boy by normal vaginal delivery weighing 3.400kg in June 2009, when mum was 40 years old.

Case C – repeat attempt

- Second attempt in February 2010
- Same treatment approach successfully conceived by September 2010.
- Delivered a second healthy boy at term 19th May 2011
 - Mum 42 years old.

Case C – Comments

- We continued Naltrexone throughout pregnancy in this case because the patient felt dramatically better preconception with treatment.
- It appears she had significant endorphin deficiency which needed ongoing treatment
- Over 200 pregnancies with naltrexone

Case 2

- 6 Recurrent Miscarriages

G.C. - 6 Miscarriages

- Presented Feb 2005
- Female 33yrs. Male 40yrs.
- G6 SA6 from Oct 02 – Jan 05
 - Miscarriage at 5 to 9 weeks each time

G.C. - 6 Miscarriages

- Dx:
 - Balanced Translocation Ch 7 and 18
 - 30% miscarriage risk every time
 - 5% risk abnormal baby
- Additional Dx:
 - Uterine Fibroid – 2 x 3cm anterior fibroid

G.C. - 6 Miscarriages

- Normal clotting
- Normal day 21 progesterone
- Unexplained why 6 miscarriages?

Chart 105 F F F F F

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35			
TAMP	Red	Red	Red	Red	Red	Red	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green		
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TAMP	Red	Red	Red	Red	Red	Red	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green		
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TAMP	REMINDER: ORDER NEW CHART, STAMPS AND MAKE APPOINTMENT FOR FOLLOW-UP																																					
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Taking a supplement for my crazy knees
 2nd cycle was not normal.
 BAD PMS
 Fibroid? (Bleed)
 VENTOLIN + STEROID
 INHALER?
 2 of miscarriages were empty pregnancy sacs almost.

G.C. - 6 Miscarriages

- Additional Problems with NPT
 - Moderate PMT symptoms for 7 days
 - Abnormal bleeding
 - Low Progesterone on P+7

- Query “Some immune factor?”

Cher 1 05 F F F F F Aug 10 est.

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35		
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DATE																																					

Rx: Pre-conception

Letrozole 2.5mg for 5 days from day 3

Luteal HCG 2,500 P+3,5,7,9

Chart 105 F F F F F

Aug 1008

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35			
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P - 86.3 nmol/l
E - 677 pmol/l

P - 59.7 nmol/l
E - 676 pmol/l

P - 78.1 nmol/l
E - 950 pmol/l

REMINDED ORDER NEW CHART, STAMPS AND MAKE APPOINTMENT FOR FOLLOW-UP

FIBROID? (Blood)
VENTOLIN + STEROID
INHALES?

to why craky knees
2nd cycle was not
normal
BAD PM

USE THESE SIGNS: P = PEAK • 1.2.3 = FERTILE DAYS FOLLOW

2 of us...
empty pregnancy sac

Chart 105 F F F F F

Aug 1008

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35					
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TAMP	REMINDED: ORDER NEW CHART, STAMPS AND MAKE APPOINTMENT FOR FOLLOW-UP																																							
Date																																								
Portion																																								

P - 86.3 nmol/l
E - 677 pmol/l

P - 59.7 nmol/l
E - 676 pmol/l

+ive test

P - 78.1 nmol/l
E - 950 pmol/l

Fibroid? (Blood)
VENTOLIN + STEROID
INHALES?
2 of us use...
empty pregnancy sac

to my craky knees
2nd cycle was not
normal...
BAD PM since x2

USE THESE SIGNS: P = PEAK • 1.2.3 = FERTILE DAYS FOLLOW

G.C. - 6 Miscarriages

- Rx: Post-conception
 - Gestone 200mg im twice weekly
 - HCG 5000 sc twice weekly
 - Prednisolone 5mg daily

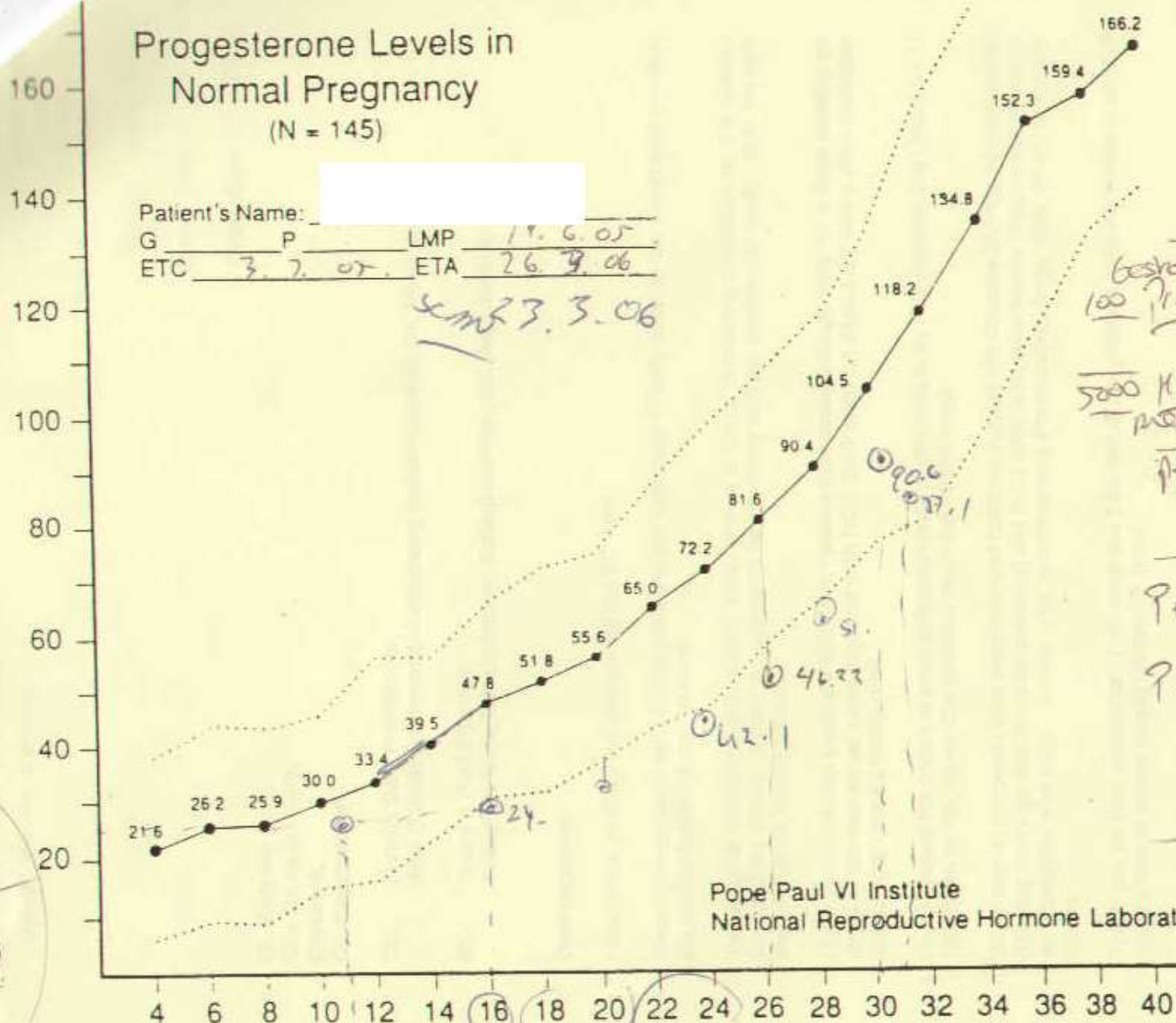
Progesterone Levels in Normal Pregnancy

(N = 145)

Patient's Name: [REDACTED]
 G _____ P _____ LMP 17.6.05
 ETC 3.7.07 ETA 26.9.06

Scanned 3.3.06

Progesterone Level (ng/ml)



Pope Paul VI Institute
National Reproductive Hormone Laboratory

Gestone 100 Prog
 5000 HCG (iml)
 Preg 24 DAILY

P+7 - P - 78
 E - 950
 P+17 - P - 70.4 (22.0)
 E - 2736

Weeks Gestation



G.C. - 6 Miscarriages

- Rx: Post-conception
 - Gestone 200mg im twice weekly
 - HCG 5000 sc twice weekly
 - Prednisolone 5mg daily
- Continued treatment until 35 weeks

G.W. - 6 Miscarriages

- **Baby Boy @ 37 weeks gestation**
- **6th March 2006**
- **5lb 5oz**
- **NVD – with Vacuum**

- **Mum and Baby are well!**

G.C. - 6 Miscarriages with LDN

- Returned for *another attempt* Aug 2006

G.W. - 6 Miscarriages

- Conceived subsequently again
 - With treatment pre-conception
 - Adjusted treatment
 - LDN (Low Dose Naltrexone)

G.W. - 6 Miscarriages

- **Previous Problems**

Needed to continue treatment throughout pregnancy

Low Progesterone persisted

Baby smaller than avg. 5lb 5oz

G.C. - 6 Miscarriages

- Add New Immune modifying treatment
 - LDN – Low Dose Naltrexone 4.5mg nightly

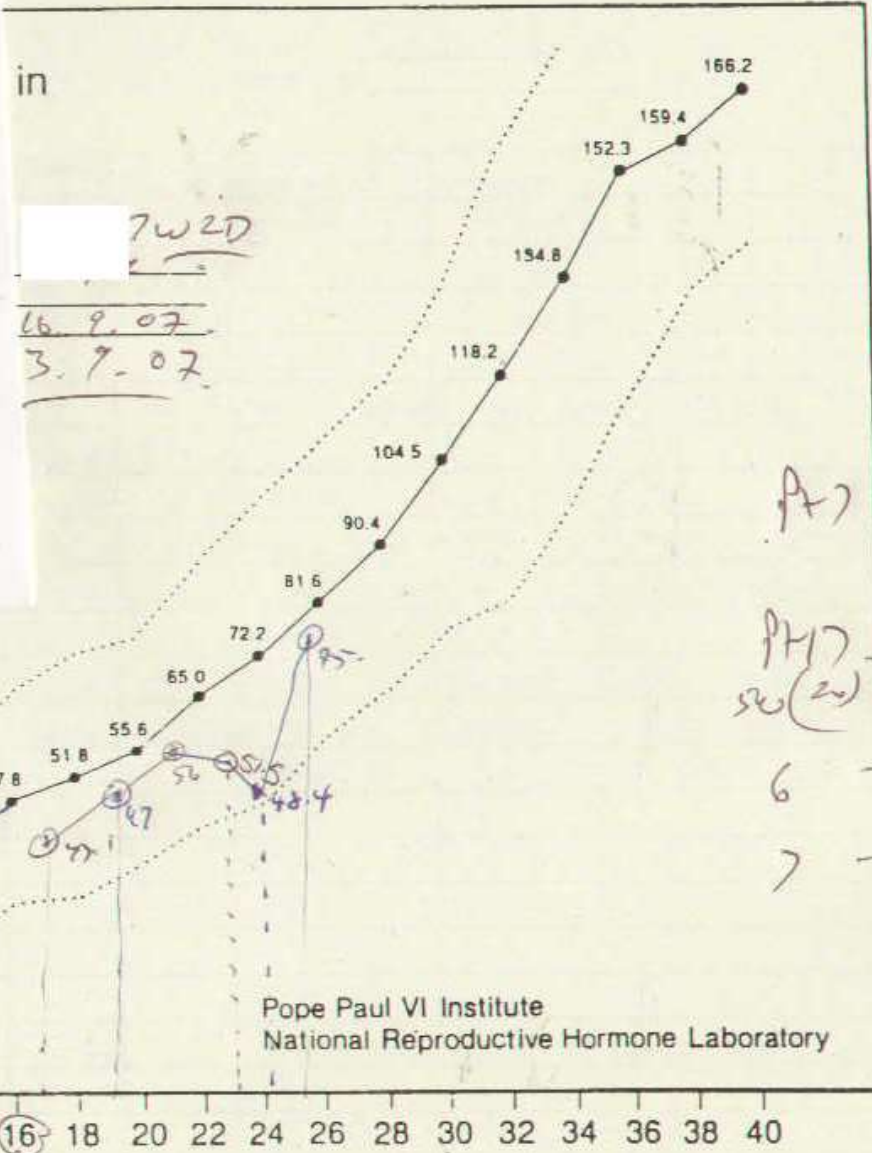
G.W. - 6 Miscarriages

- Hoped

**Less need to continue progesterone treatment
throughout pregnancy**

Better Progesterone levels

Bigger baby



3.18

Weeks Gestation

Cyclogest
Twice daily

P47 - N/A
 P47
 101 (31.9)
 6 - 118 (37)
 7 - 109 (34)

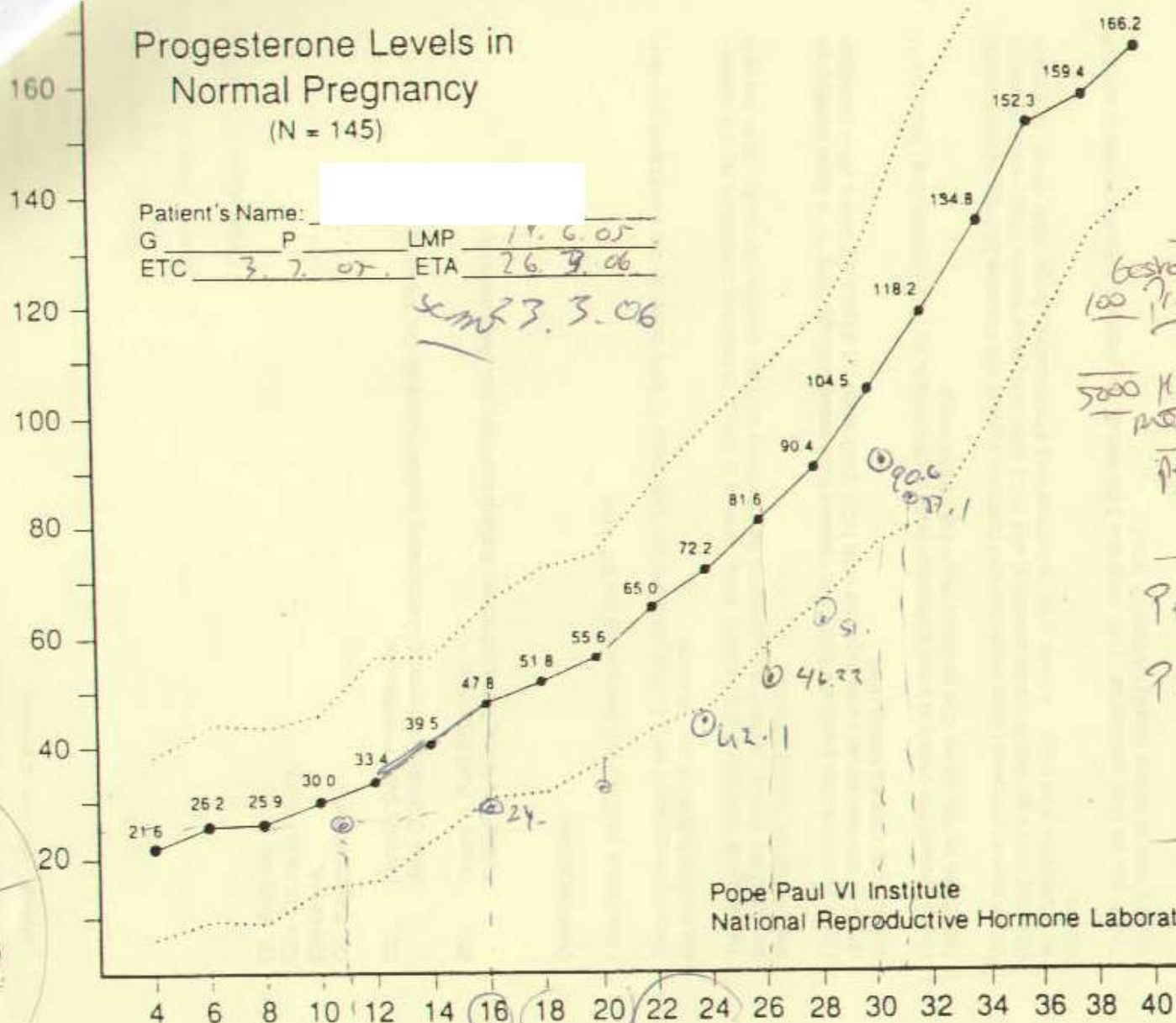
Progesterone Levels in Normal Pregnancy

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 ETC 3.7.07 ETA 26.9.06

Scanned 3.3.06

Progesterone Level (ng/ml)



Pope Paul VI Institute
National Reproductive Hormone Laboratory

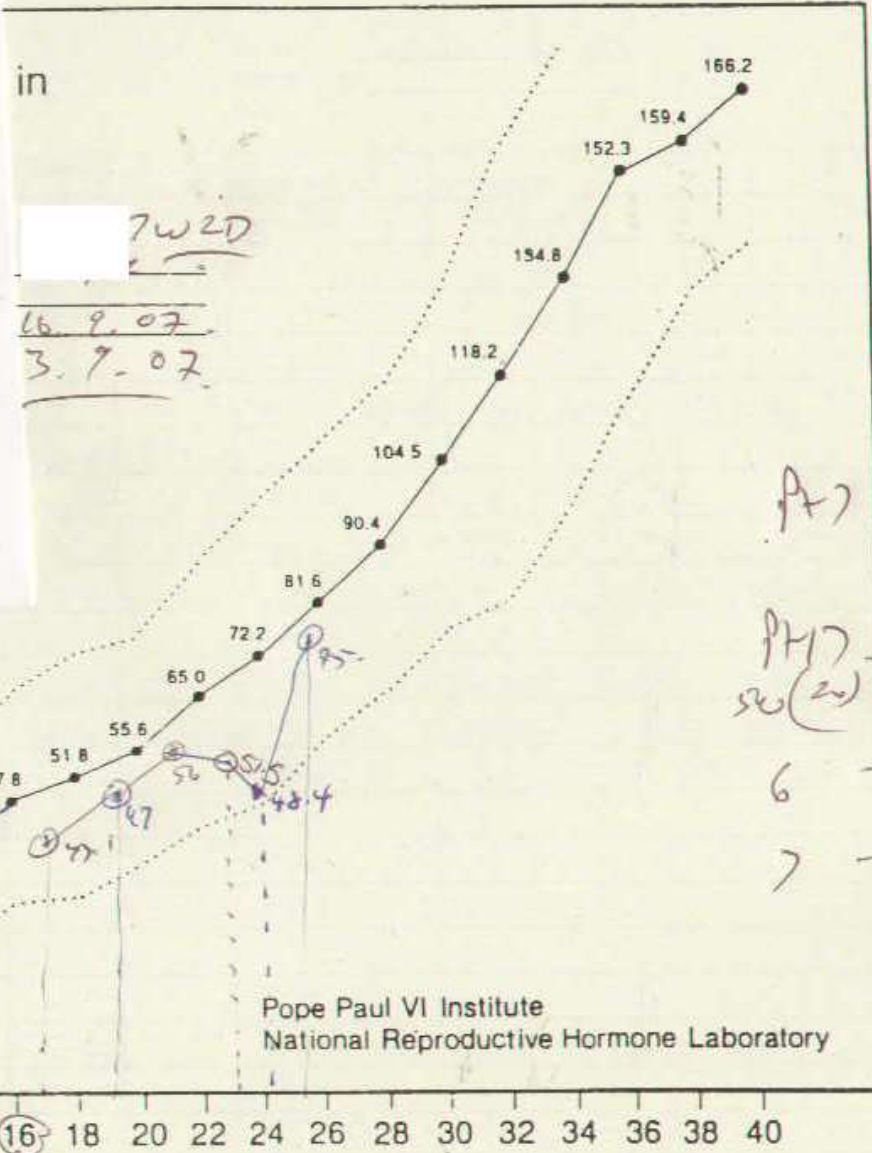
Gestone 100 Prog
 5000 HCG (ml)
 Preg
 DAILY

P+7 - P - 78
 E - 950
 P+17 - P - 70.4 (22.0)
 E - 2736

Weeks Gestation

3-18

100
100



3.18

Weeks Gestation

Cyclogest
Twice daily

P47 - N/A
 P47 101 (31.9)
 56 (20) 118 (37)
 6 -
 7 - 109 (34)

G.W. - 6 Miscarriages

- **Successful pregnancy**
 - **Female 7lb 3 oz**
 - **Full term**
 - **NVD Sept 2007**



A New Low Dose Naltrexone - LDN

- **Compounding Pharmacist**

- **Dose**

- 1.5mg, 3.0mg or 4.5 mg fast release tablet nightly before sleeping (9pm -2am)

A New Low Dose Naltrexone - LDN

- This will give a 3 fold increase in beta endorphin levels.

A New Low Dose Naltrexone - LDN

- Improving Endorphin Levels
 - Has a “Stimulatory effect” on the immune system
 - Improves immune function

A New Low Dose Naltrexone - LDN

- Improving Endorphin Levels
 - Halts the progression of HIV
 - Halts the immune system when it begins to attack “SELF” (Auto-immune illness)
 - Reduces Lifetime risk of developing cancer

Low Dose Naltrexone - LDN

- Obviously fantastic treatment
 - Low toxicity – “first do no harm”
 - Inexpensive
 - Seems Effective Clinically
 - Easy to take
 - No Need for specialised Physician training
 - Few Ethical issues
- Anticipate widespread use and acceptance very quickly

Low Dose Naltrexone - LDN

- Surprise!!



- Huge resistance among many doctors to even try it out!

Doctor Resistance

- Unlicensed for Auto-immune disorders
- Experimental treatment
- Not “evidence based” medicine
- Doctors not covered by medical insurance

- Too Risky!



Up the Creek with a Paddle

Beat MS and Many
Autoimmune Disorders with
Low Dose Naltrexone (LDN)

Mary Anne Boyle Bradley

Infertile 36y female with R.Arth.

- **Diagnosis of PCOD and 10 years of Infertility, previous success in our programme**
- **First episode of Acute onset of R. Arth.**
 - **When trying to conceive for the second time**
- **Diagnosed by Rheumatologist**
- **Resistant to NSAIDS**
- **Advised – Methotrexate (then cannot conceive!)**

Infertile 36y female with R.Arth.

■ LDN

- Rapid 80% improvement in symptoms
- No Side effects
- Conceived after 2 cycles of LDN and other fertility treatment

- Successful pregnancy

Case Presentations

- Premenstrual Syndrome
- Severe Bipolar Disorder
- The Future.....Pre-Treatment!



Endometriosis 27 yr old single female

- Dx Age 18
 - 5 laparoscopies
 - Oral Contraceptive Pill
 - Zoladex x 3 years – made pain bearable
- Deferred University studies



Endometriosis 27 yr old single female

- Depression
- Profound fatigue
- Underactive thyroid
- Anxiety
- Joint pain
- Severe PMS 7 days each cycle & brown menstrual bleeding

Hospitalised repeatedly for investigation and treatment of pain



Endometriosis 27 yr old single female

- 2007 – Started NaPro
- LDN 4.5mg nightly
- Diet – based on IgG antibody testing



Endometriosis 27 yr old single female

- It has completely changed my life
- For the first time in a long time, I can say I have a life



Endometriosis 27 yr old single female

- Depression - gone
- Profound fatigue - gone
- Underactive thyroid - on a lower dose of medication
- Anxiety - gone
- Joint pain - gone
- Severe PMS 7 days each cycle – now 2 days and mild
- brown menstrual bleeding - gone
- Pain -



Endometriosis 27 yr old single female

- A complete transformation has occurred physically, mentally and emotionally
- For the first time in my life I feel like a complete human being and not a multitude of symptoms
- I was helpless and a hopeless case before this treatment

Bipolar Disorder - 28 year old female

- On Lithium for 10 years
 - Previously hospitalised
 - Trying to conceive and wean off lithium
 - Part of treatment included LDN
-
- Delivered 3 years ago 2010 – Never had a relapse
 - Maintained on LDN



The Future.....

- 31yo G0 P0 – 1st Visit Feb 2008
- Engaged – wedding July 2008
 - +++PMS, Fatigue,
 - +FH – Sister PCOS
- Not Sexually Active
- Not trying to conceive ...yet!

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USE THESE SIGNS: P = PEAK • 1,2,3 = FERTILE DAYS FOLLOWING PEAK • I = INTERCOURSE BE = BREAST SELF-EXAM

B6+10mg x2



The Future.....

- Peak +7
 - Low Progesterone
 - Low Oestradiol
- Endorphin Deficiency



The Future.....

- Treatment
 - Cyclogest Peak +3 for 10 nights
 - Naltrexone 4.5mg



The Future.....

- Treatment
 - Improved Progesterone
 - PMS gone
 - Energy and mood improved

- But.....still abnormal bleeding...



The Future.....

- Ultrasound May 08.....

Ⓟ

22 + 14 + B.

Ⓟ Fall-12



700.



? Polyp



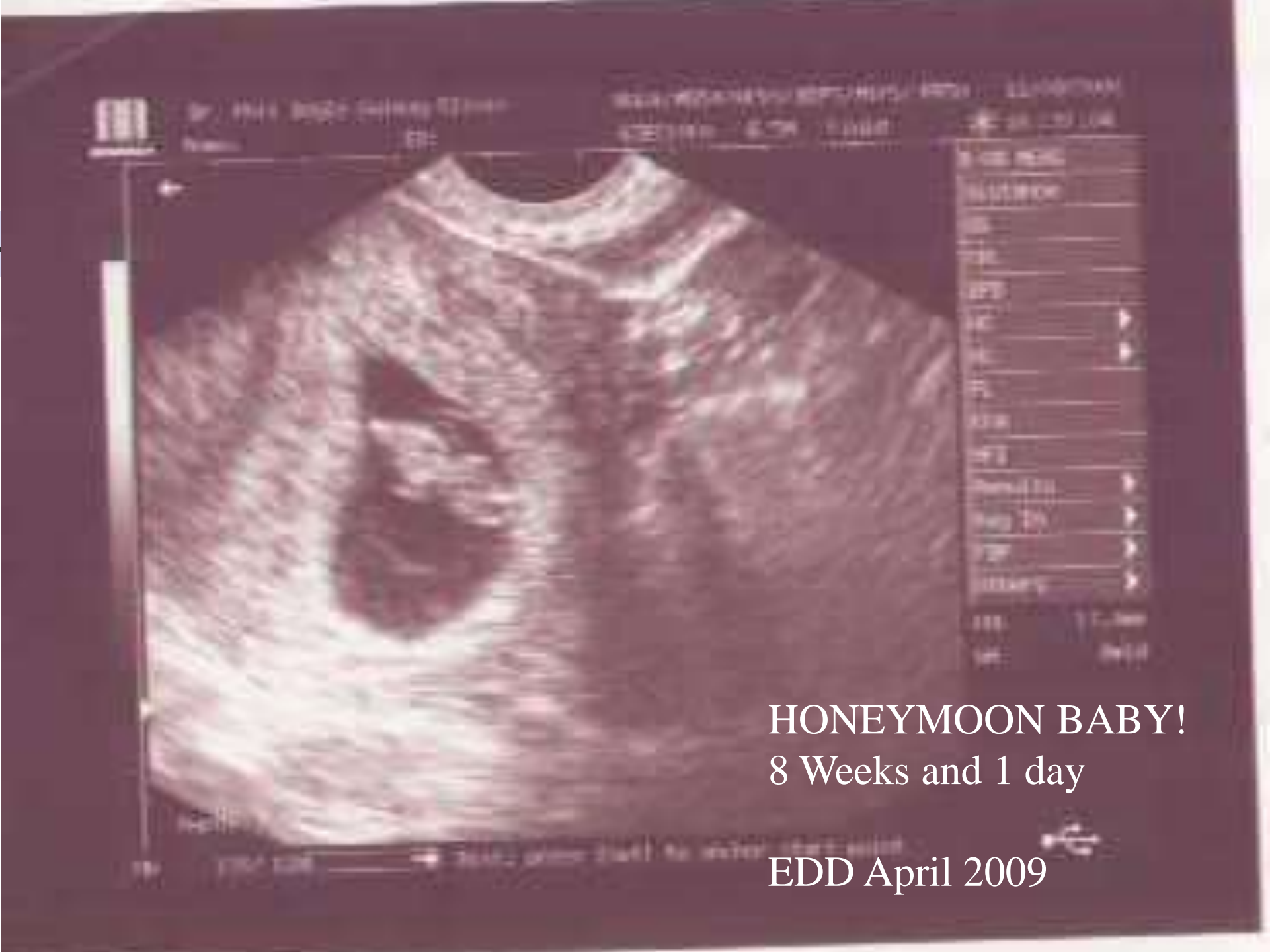
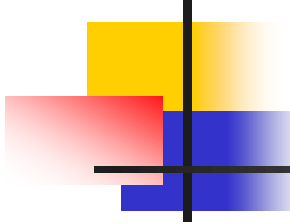
The Future.....

- Ultrasound May 08
 - PCOS
 - Endometrial Polyp
- Surgical referral
 - Hysteroscopy & Polypectomy July 08



The Future.....

- Healthy and Happy
 - PMS, Energy
- Normal Chart
 - Bleeding, Mucus
- Normal hormones
 - Progesterone, Oestradiol



HONEYMOON BABY!
8 Weeks and 1 day
EDD April 2009



The Future.....

Problem was identified and solved
.....even before it officially existed!

What would have happened
without LDN and
NaProTechnology?



The Future.....for LDN

It is safe....

- Doctors need to consider the mounting clinical and published evidence in favour of LDN!
- Proven Immune modifying treatment Placebo RCT.

Restore normal function



Any Questions?



Dr. Phil Boyle

