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Effect of vaginally administered docosahexaenoic acid (DHA) fatty acids on pregnancy outcome

Submission date 27/05/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 04/08/2009	**Overall study status** Completed	
Last Edited 04/08/2009	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IRS - 09 - 0001

Study information

Scientific Title
Effect of vaginally administered docosahexaenoic acid (DHA) fatty acids on pregnancy outcome: a randomised controlled trial

Study objectives
Until today supplementation in pregnancy is performed only with sources consumed per os. Moreover, trials for prevention of premature delivery or low weight baby uses docosahexaenoic acid (DHA) administered orally. The metabolism and absorption of lipids in the gastrointestinal tract is related to a complex pathway involving liver, pancreatic and gastric enzymes. This mechanism could lead to a loss of concentration in the blood that could causes in turn a low effective concentration. The purpose of our study is to assess the efficacy of DHA administered vaginally.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee of the "Artemisia Medical Institute Network" (created according to the guidelines reported in the "Decreto Ministeriale (DM) 15/7/1997", Ministry of Health of Italy) on the 11th April 2009

Study design
Single centre double-blind randomised placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Low birth weight, preterm labour, hypertension in pregnancy, gestational diabetes

Interventions
Iintervention group: vaginally 3 g fish oil (1 g DHA) daily for 20 weeks starting until delivery
Control group: vaginally 3 g placebo used as above

Intervention Type
Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)
Docosahexaenoic acid (DHA) fatty acids

Primary outcome measure
1. Timing of pregnancy
2. Newborn weight

Both endpoints will be measured at the end of the trial. No interim analysis will be performed.

Secondary outcome measures
1. Hypertensive disorders
2. Diabetes

Both endpoints will be measured at the end of the trial. No interim analysis will be performed.

Overall study start date
01/09/2009

Completion date
31/05/2010

Eligibility

Key inclusion criteria
All women with a viable foetus between 18+0 and 24+0 weeks of gestation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
60

Key exclusion criteria
1. History of placental abruption
2. Bleeding episode in the present pregnancy
3. Women using (or used) prostaglandin inhibitors
4. Multiple pregnancy
5. Allergy to fish
6. Regular intake of fish oil

Date of first enrolment
01/09/2009

Date of final enrolment
31/05/2010

Locations

Countries of recruitment
Italy

Study participating centre
Viale Liegi, 45
Rome
Italy
00198

Sponsor information

Organisation
Italian Society of Prenatal Diagnosis and Fetal Maternal Medicine (S.I.Di.P.) (Italy)

Sponsor details
Viale Liegi, 49
Rome
Italy
00198

Sponsor type
Research organisation

Website
http://www.ilfeto.it/

Funder(s)

Funder type
Industry

Funder Name
Pharmarte Srl (Italy)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration