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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

Contact name
Prof Claudio Giorlandino

Contact details
Viale Liegi, 45
Rome
Italy
00198

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Single centre double-blind randomised placebo controlled trial

Study type(s)
Treatment

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(s)
1. Timing of pregnancy
2. Newborn weight

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

Key secondary outcome(s)
1. Hypertensive disorders
2. Diabetes

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

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)

Funder(s)

Funder type
Industry

Funder Name
Pharmarte Srl (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration