

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

Submission date 27/05/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 04/08/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/08/2009	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Intervention 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