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CORDHA study: Optimization of the viability of stem cells derived from umbilical CORd blood after maternal supplementation with docosahexaenoic acid (DHA) during the second or third trimester of pregnancy

Submission date
18/09/2013

Recruitment status
No longer recruiting

Registration date
08/10/2013

Overall study status
Completed

Last Edited
03/06/2014

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The umbilical cord blood is an important source of hematopoietic stem cells (the blood cells that give rise to all the other blood cells). However, the amount of cells in the cord blood units is limited and this may restrict their clinical use. The cell viability (ability of the cell to survive) of an umbilical cord blood sample measures the percentage of the metabolic active stem cells. It follows that an active cellular metabolism causes increased production of stem cells, offering an opportunity to increase the number of cells. A high cell dose is essential when transplanting cord stem cells, guaranteeing a successful outcome in the receiving person. This study is designed to evaluate the impact of docosahexaenoic acid (DHA) supplementation in pregnant women, in order to increase the quantity and viability of the cells in the umbilical cord blood samples.

Who can participate?
Women aged >18 years and absence of: diabetes, high blood pressure (hypertension) or any other type of health problems requiring intake of medicines, genetic diseases, chromosome abnormalities and/or congenital malformations in the foetus and the absence of infectious disease (hepatitis B, hepatitis C, HIV and cytomegalovirus).

What does the study involve?
Participants are randomly allocated to receive either placebo (dummy) or DHA (250 mg) one a day from the 20th week or DHA (250 mg) one a day from the 28th week up to the 40th week. Cell number and cellular viability are evaluated within 48 hours of the collection of the umbilical cord blood sample.

What are the possible benefits and risks of participating?
Participants receiving DHA may benefit from an increased amount of stem cells being collected in the umbilical cord blood samples at birth. At the moment there are no risks related to the use of DHA during pregnancy.

Where is the study run from?
The study has been set up by the SmartBank in collaboration with San Giovanni Calibita FatebeneFratelli-Roma hospital. 62 pregnant women will be recruited from those using the Gynaecological and Obstetrics Service of the San Giovanni Calibita FatebeneFratelli-Roma hospital, and 88 will be selected from the SmartBanks clients.

When is the study starting and how long is it expected to run for?
The recruitment started in 2010 and participants will be enrolled on the study for a period of four years.

Who is funding the study?
This study is supported by SmartBank s.r.l., BioVault Ltd and Avantgarde s.a.s

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
A randomised controlled trial for the optimization of the viability of stem cells derived from umbilical CORd blood after maternal supplementation with DHA during the second or third trimester of pregnancy

Acronym
CORDHA

Study objectives

This study is designed to evaluate the impact of the DHA supplementation in pregnant women during the second (20th week of estimated gestational stage) or the third (28th week of estimated gestational stage) trimester of pregnancy, in order to increase the quantity and viability of the cells, in particular of the haematopoietic lineage, in the umbilical cord blood samples collected at birth.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of the FateBeneFratelli San Giovanni Calibita Hospital - Isola Tiberina, 09/07/2009, ref: 35/2009; and 09/12/2010, ref: 67/2010

Primary study design
Interventional

Study design
Four years randomised double blind monocentric study

Study type(s)
Screening

Health condition(s) or problem(s) studied
Increase the quantity and viability of the stem cells, in the umbilical cord blood samples in pregnant women supplemented with DHA.

Interventions
150 pregnant women will be recruited from the Gynaecological and Obstetrics Service of the San Giovanni Calibita FatebeneFratelli-Roma hospital, and from the SmartBanks clients. Each participant receives a complete set of capsules of either placebo (250 mg of olive oil) or DHA (250 mg), to take one a day from the 20th or from the 28th week up to the 40th week of estimated gestational age.

The DHA capsules (active batch) contain 250 mg IncromegaTM DHA 250TG SR+10 mg natural VIT E (Avantgarde sigma-tau, Rome, Italy). The DHA in the capsule is extracted from fish oil by PureMaxTM technology that enables lipids to be purified and concentrated to maximum standards. This ensures that the DHA used for this study is free of contaminants (heavy metals such as mercury, arsenic, cadmium, lead; oxidant impurities, dioxins and furans, dioxin-type polychlorinated biphenyls, polycyclic aromatic hydrocarbons). The packaging of the capsules in the two groups is identical. Additionally, all participants receive a free cord blood collection kit provided by SmartBank (SmartBank Rome, Italy). Hospital staff assisting the birth immediately extract and collect the cord blood with the kit. Samples are shipped to the BioVault laboratory (BioVault technical laboratory, Plymouth, UK) for specific analysis: volume (ml), pH, cell viability (%), number of CD34+ cells, number of leukocytes, bacterial and viral tests. When possible, 2 cc of the extracted cord blood are sent to the Lipinutragen-CNR laboratory in Bologna to determine the DHA percentage in the cord blood erythrocyte membranes.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
docosahexaenoic acid

Primary outcome(s)
Measure of the viability (%) and the number of CD34+ cells collected from the umbilical cord blood at birth from the patients treated with placebo or DHA from the 20th or from the 28th week.

Key secondary outcome(s)
Understand which stage of the supplementation with DHA (the second or the third trimester of pregnancy) is more effective in terms of quantity and viability of the stem cells, in the umbilical cord blood samples.

Completion date
01/09/2014

Eligibility

Key inclusion criteria
1. Age >18 years
2. Absence of: diabetes, hypertension or any other type of pathology requiring pharmacological therapy, genetic diseases, chromosome abnormalities and/or congenital malformations in the foetus and the absence of infectious disease (hepatitis B, hepatitis C, HIV and cytomegalovirus).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. Age <18 years
2. Presence of: diabetes, hypertension or any other type of pathology requiring pharmacological therapy, genetic diseases, chromosome abnormalities and/or congenital malformations in the foetus and the presence of infectious disease (hepatitis B, hepatitis C, HIV and cytomegalovirus).
3. Cord blood samples with a volume of less than 80 ml and/or less than 70% cell vitality are excluded from the study.

Date of first enrolment
01/09/2010

Date of final enrolment
01/09/2014

Locations

Countries of recruitment
Italy

Study participating centre
Via Vittorio Locchi, 9
Rome
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Sponsor information

Organisation
SmartBank (Italy)

Funder(s)

Funder type
Industry

Funder Name
Private funds from SmartBank, the stem cells bank (Italy)

Funder Name
BioVault Ltd (Italy)

Funder Name
Avantgarde s.a.s (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/05/2014		Yes	No