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Probiotics effective against preterm delivery

Submission date	Recruitment status	[_] Prospectively registered
27/09/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/11/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/01/2019	Pregnancy and Childbirth	

Plain English summary of protocol

Background and study aims
Preterm delivery (i.e., giving birth before 37 weeks of pregnancy) is a leading cause of illness and death in newborn babies. It often results from infections caused by changes in the vaginal microbiota - the microorganisms found in the vagina. Probiotics are live microorganisms that may be able to help prevent and treat some illnesses. Probiotics were found to be effective at treating vaginal infections in non-pregnant women, but there have been no studies in pregnant women. The aim of this study is to find out the effects of taking a commercially available probiotic tablet in routine antenatal care.

Who can participate?
Pregnant women aged over 18 years at less than 12 completed weeks of pregnancy.

What does the study involve?
Participants are randomly allocated to one of two groups. One group takes one probiotic capsule every day for 8 weeks. The other group takes a placebo (dummy) capsule every day for 8 weeks. Two vaginal swabs are taken before and after the treatment to assess the vaginal microbiota, and participants complete questionnaires over the telephone.

What are the possible benefits and risks of participating?
Probiotics have already been used during pregnancy and seem to be safe. The possible benefits are positive effects on the vaginal microbiota which may act against infections.

Where is the study run from?
University Children's Hospital Tübingen (Germany).

When is the study starting and how long is it expected to run for?
October 2010 to May 2012.

Who is funding the study?
University Children's Hospital Tübingen (Germany).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1.1

Study information

Scientific Title
Randomised controlled trial, pilot study: changing vaginal microflora of pregnant women by oral probiotics

Acronym
EFFPRO-Pilot

Study objectives
Daily oral intake of probiotic lactobacilli strains (L. rhamnousus GR-1 and L. fermentum RC-14) will lead to a reduction of pathologic vaginal microflora and increased number of lactobacilli in the vaginal flora. We aim to demonstrate that an intervention delivered via the public health care system is effective and well accepted by pregnant women.

On 30/09/2015 the following changes were made to the trial record:
1. The overall trial end date was changed from 04/02/2011 to 04/02/2013.
2. The target number of participants was changed from 60 to 320.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Ethics Committee of the Medical Faculty of the University of Tuebingen, 02/07/2010, ref: 238/1010B01
2. An amendment of the study protocol was approved on 24/11/2010

Primary study design
Interventional

Study design
Randomised triple-blind placebo-controlled parallel-group trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pregnant women with abnormal vaginal flora

Interventions
1. Experimental Group: Daily oral intake of one capsule containing Lactobacillus rhamnosus GR-1 (GR-1®) and Lactobacillus reuteri RC-14 (RC-14®). The dosage at end-of-shelf-life is 1 × 109 colony forming units of each strain per capsule. The intake will last for 8 weeks, starting individually after the participants first routine antenatal visit after enrolment. Both, verum and placebo will be provided by Chr. Hansen A/S (DK-2970 Hørsholm, Denmark). The verum product is licensed and sold as a food supplement in Europe (Probio-Tec® UREX-cap-5), including Germany (Femibion® Flor Intim).
2. Control group: Daily oral intake of one capsule placebo. The intake will start and end according to the intervention group. Verum and placebo will be provided in identical packing by the drug manufacturer. Placebo capsules will be similar to probiotic capsules and will not be distinguishable from verum, neither by visual inspection nor by taste.

Intervention Type
Other

Phase
Phase IV

Primary outcome(s)
Restoration from asymptomatic pathologic vaginal flora to a normal lactobacilli colonisation and an increase in lactobacilli in the vaginal flora after 8 weeks of intervention.

Key secondary outcome(s)
None

Completion date
04/02/2013

Eligibility

Key inclusion criteria
1. Pregnant women, resident within the study area at the time of enrolment and being attending a medical practice located within the study area (A random selection process will assure representativeness of recruiting practices and, hence, external validity)
2. Over 18 years
3. Less than 12 completed weeks of pregnancy (WOP)
4. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. Active chronic inflammatory bowel disease (M. Crohn, Colitis ulcerosa)
2. Immunodeficiency

Date of first enrolment
04/10/2010

Date of final enrolment
31/05/2012

Locations

Countries of recruitment
Germany

Study participating centre
University Children's Hospital Tübingen
Tuebingen
Germany
72076

Sponsor information

Organisation
University Children's Hospital Tübingen (Germany)

ROR
https://ror.org/03esvmb28

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Children's Hospital Tübingen (Germany) - Department of Neonatology, internal funding

Funder Name
There is no co-financing by industry and/or other third parties. However, study drugs will be provided for a small fee by Chr. Hansen, Denmark.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2016	18/01/2019	Yes	No