ISRCTN14702259 https://doi.org/10.1186/ISRCTN14702259

Efficacy and safety for women and their unborn babies using misoprostol as a vaginal insert to induce labour for women past 40 weeks of pregnancy

Submission date
01/06/2020

Recruitment status
No longer recruiting

Registration date
21/08/2020

Overall study status
Completed

Last Edited
04/03/2022

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
One of the most common reasons for inducing labour is a prolonged pregnancy. Prostaglandins (a chemical that is produced in the body) have been proven to induce labour. A drug that can be given to induce labour called misoprostol vaginal insert (MVI) was available in Germany from 2014 to 2019. This study has the aim to clarify whether MVI is safe and efficient for women with prolonged pregnancies (40 to 42 weeks) due to the lack of studies focussing on this particular group of women.

Who can participate?
Pregnant women aged 18 years or above who are 40 or more weeks pregnant.

What does the study involve?
Participants will receive the MVI to induce labour and are closely monitored by the healthcare staff until the baby is delivered.

What are the possible benefits and risks of participating?
None. Treatment is given as usual.

Where is the study run from?
Presbitarian Hospital Bergisch Gladbach (Germany)

When is the study starting and how long is it expected to run for?
January 2014 to September 2019.

Who is funding the study?
Lutheran-Protestant (EVK) Hospital Bergisch Gladbach (Germany)

Who is the main contact?
Prof. Christian Rudlowski, rudlowski@t-online.de

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MISO-001

Study information

Scientific Title
Efficacy and safety of misoprostol vaginal insert to induce labour in pregnancies beyond 40+0 weeks of gestation

Study objectives
Misoprostol vaginal insert is save and efficient for women with prolonged pregnancies

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/01/2014, Local Ethic Commitee, EVK Bergisch Gladbach (Ferrenbergstrasse 24. 51465 Bergisch Gladbach, Germany; +49 22021221088; seelsorge@evk.de), ref: none provided

Study design
Observational cohort study non-interventional

Primary study design
Observational

Secondary study design
Cohort study

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 in German

Health condition(s) or problem(s) studied
Induction of labour in women with prolonged pregnancies

Interventions
All women participating in our study gave informed consent. All patients are induced to labour at 40 and more weeks of gestation based on their first-trimester ultrasound examination. Baseline demographic data is collected which includes age, parity, gestational age, gestational diabetes and BISHOP scores, among others. Labour is induced with Misodel® (approved by the European Medicines Agency [EMA]). Prior to the misoprostol vaginal insert application, every woman has a cardiotocography for thirty minutes. A vaginal examination is performed before the vaginal insert placed to determine the cervical ripeness.
Misoprostol is placed in the posterior vaginal fornix and removed within 24 h. Indications for removing misoprostol are either the onset of labour (three or more contractions in 10 min), a cervical dilatation of 4 cm, hyper frequency contractions or after an exposure time of not more than 12 h. All women will have another cardiotocography after MVI removal. The time period from (1) insertion to the onset of labour, (2) onset of labour until delivery and (3) duration from insertion to birth is observed.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Misodel (misoprostol)

Primary outcome measure

Measured using case report forms:
1. Time from insertion to the onset of labour (hours)
2. Time from onset of labour until delivery (hours)
3. Time from insertion to birth was measured (hours)

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
03/01/2014

Completion date
01/09/2019

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. No prior history of Caesarean section
3. Prolonged pregnancy requiring induction of labour

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
300

Total final enrolment
304

Key exclusion criteria
Contraindications for prostaglandins

Date of first enrolment
01/12/2014

Date of final enrolment
01/09/2019

Locations

Countries of recruitment
Germany

Study participating centre
EVK Hospital Bergisch Gladbach
Department of Obstetrics
Ferrenbergstrasse 24
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Sponsor information

Organisation
Lutheran-Protestant Hospital (EVK)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.evk.de

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
EVK Bergisch Gladbach

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/08/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results		16/09/2020	04/03/2022	No	No