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	Recruitment status No longer recruiting	Prospectively registered		
01/06/2020		☐ Protocol		
Registration date 21/08/2020	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
04/03/2022	Pregnancy and Childbirth			

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)

Contact information

Type(s)

Scientific

Contact name

Prof Christian Rudlowski

Contact details

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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 Bergisch Gladbach Germany 51465

Sponsor information

Organisation

Lutheran-Protestant Hospital (EVK)

Sponsor details

Ferrenbergstr 24 Bergisch Gladbach Germany 51465 +49 22021222400 frauenklinik@evk.de

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