

Intravaginal APL202 versus dinoprostone in the induction of labour in multiparous subjects

Submission date 15/01/2010	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 15/01/2010	Overall study status Completed	☐ Protocol
Last Edited 29/01/2010	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
APL202-002

Study information

Scientific Title
A randomised open comparison of intravaginal APL202 (25 µg) followed by 25 µg after 4 and 8 hours versus 3 mg of dinoprostone as a vaginal tablet followed by 3 mg after 6 hours in the induction of labour in multiparous subjects

Study objectives

The objective of study APL202-002 was to determine the safety and efficacy of APL202 in the induction of labour of multiparous subjects compared with the standard agent currently used for cervical ripening.

The trial was previously registered at Pharmaceutical Industry Clinical Trials Database (ABPI /CMR) - <https://www.cmrinteract.com/clintrial/default.htm>.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South East Multi-centre Research Ethics Committee approved on the 4th November 2004 (ref: 04 /MRE01/45)

Study design

Randomised open comparative non-inferiority study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Induction of labour - multiparous subjects

Interventions

This was an open, comparative study to determine the safety and efficacy of APL202 in the induction of labour of multiparous subjects compared with dinoprostone, the standard agent for the induction of labour. Each subject was assigned to receive either:

1. APL202 25 µg intravaginally followed by APL202 25 µg intravaginally after 4 and 8 hours, or
2. Dinoprostone 3 mg intravaginally followed by dinoprostone 3 mg intravaginally after 6 hours

The statistical section of the APL202-002 protocol was amended during the course of the study to note that a two-sided analysis would be performed, in line with revised guidelines from the EMEA (Guideline on the choice of the non-inferiority margin, EMEA).

Subjects were randomised equally to each treatment with 506 subjects scheduled to be recruited in conjunction with the same number of subjects in a parallel study APL202-001 (506 were due to be randomised to each treatment). However, a decision was made in 2006 with the agreement of the ethics and regulatory authorities to pool the data from this study and study APL202-001. This meant that a combined total of 622 subjects, with not more than two-thirds and not less than one-third from either study, were required to be enrolled.

Scientific Contact Details - Lead Principal Investigator:

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Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

APL202, dinoprostone

Primary outcome(s)

Number of vaginal deliveries within 24 hours of the start of induction

Key secondary outcome(s)

1. Number of vaginal deliveries within 12 hours of the start of induction
2. Number of caesarean section deliveries
3. Mean induction-delivery interval
4. Distribution of induction-delivery interval
5. Oxytocin augmentation requirement
6. Number of instrument-assisted vaginal deliveries
7. Incidence and mean duration of tachysystole
8. Uterine hyperstimulation with fetal heart rate changes
9. Pyrexia during labour
10. Serious neonatal morbidity or perinatal death
11. Serious maternal morbidity or death

Measured at differing timepoints prior to the discharge of the patients from the hospital after the delivery of the baby.

Completion date

11/03/2007

Eligibility**Key inclusion criteria**

1. Subjects, aged 18 years or over, who had at least one previous term pregnancy suitable for induction of labour with prostaglandin cervical ripening agents
2. Pregnancy duration of at least 37 weeks
3. Subjects with an unfavourable cervix defined as a Bishop Score of less than 9
4. Signed informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. Subjects requiring insulin to control their diabetes. Subjects with controlled Type II or gestational diabetes that do not require insulin may be included.
2. Subjects with a multiple pregnancy
3. Subjects in whom oxytocic drugs are generally contraindicated or where prolonged contractions of the uterus are considered inappropriate, i.e:
 - 3.1. History of caesarean section or major uterine surgery
 - 3.2. Cephalopelvic disproportion
 - 3.3. Foetal malpresentation
 - 3.4. Clinical suspicion or definite evidence of pre-existing foetal distress
 - 3.5. History of difficult labour and/or traumatic delivery
 - 3.6. Grand multiparae with over 5 previous term pregnancy
4. Subjects with an intercurrent vaginal, systemic or ascending infection
5. Subjects with clinical suspicion or definite evidence of placenta praevia or unexplained vaginal bleeding during their pregnancy. Occasional spotting, considered by the investigator to be of no clinical significance concerning the use of cervical ripening agents and having a reasonable explanation (e.g. cervical ectropion, cervical polyps), is not a reason for exclusion.
6. Subjects with active cardiac, pulmonary, renal or hepatic disease
7. Subjects with abruptio placenta. Abruptio placenta in a previous pregnancy is not a reason for exclusion.
8. Subjects with ruptured membranes
9. Subjects with a known allergy to prostaglandins or other constituents of the tablets
10. Subjects with any contraindication to vaginal delivery (e.g. active genital herpes)

Date of first enrolment

05/01/2005

Date of final enrolment

11/03/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Alliance Pharmaceuticals Ltd
Chippenham
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Sponsor information

Organisation

Alliance Pharmaceuticals Ltd (UK)

ROR

<https://ror.org/001zd1d95>

Funder(s)

Funder type

Industry

Funder Name

Alliance Pharmaceuticals Ltd (UK)

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?
Results article	results	01/09/2008		Yes	No