

ANODE: Prophylactic antibiotics for the prevention of infection following operative delivery

Submission date 23/09/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/09/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/10/2019	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Operative vaginal delivery, also known as assisted delivery, accounts for more than 10% of births in the UK. In an operative vaginal delivery, forceps or a vacuum device are used in order to help to deliver a baby during the final stages of labour. It has been found that women who have had this type of delivery have a higher risk of infection following the birth of their baby (postpartum infection). An operative vaginal delivery can cause accidental tearing of the vagina or even require a surgical incision (episiotomy) to be made; these are both possible sources of infection. Although there are concerns about over-prescribing antibiotics, it may be a good way to stop postpartum infections from developing. The aim of this study is to find out whether giving new mothers a single dose of an antibiotic after an assisted delivery could help to prevent postpartum infection.

Who can participate?

Healthy women aged 16 and over who have had an operative vaginal delivery.

What does the study involve?

Participants are randomly allocated into two groups. Those in the first group are given an injection directly into a vein (intravenous) of an antibiotic solution (amoxicillin) immediately after giving birth. Participants in the second group are given a placebo solution (salt solution with no antibiotic). When the women are discharged from hospital, signs of infection are recorded. After six weeks, participants are asked to complete a questionnaire about any problems they have experienced with pain, healing or infection.

What are the possible benefits and risks of participating?

Not provided at time of registration.

Where is the study run from?

NPEU Clinical Trials Unit, Oxford (UK)

When is the study starting and how long is it expected to run for?
September 2009 to August 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Nelly Owino
anode@npeu.ox.ac.uk

Contact information

Type(s)

Public

Contact name

Ms Nelly Owino

Contact details

NPEU Clinical Trials Unit
National Perinatal Epidemiology Unit
University of Oxford
Old Road Campus
Headington
United Kingdom
OX3 7LF

Additional identifiers

Clinical Trials Information System (CTIS)

2015-000872-89

Protocol serial number

19501

Study information

Scientific Title

ANODE: A randomised controlled trial of prophylactic Antibiotics to investigate the prevention of infection following Operative vaginal Delivery

Acronym

ANODE

Study objectives

The aim of this study is to find out if giving mothers a single dose of an antibiotic after they have had an assisted delivery helps to prevent infection.

Ethics approval required

Old ethics approval format

Ethics approval(s)

15/SC/0442

Study design

Randomised; Interventional; Design type: Not specified, Prevention

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Reproductive health and childbirth; Subtopic: Reproductive Health and Child (all Subtopics); Disease: Reproductive Health & Childbirth

Interventions

Co-amoxiclav versus placebo, A single intravenous dose (1g amoxicillin/200mg clavulanic acid in 20ml water for injections for active drug, 20ml 0.9% saline for placebo)

Intervention Type

Other

Primary outcome(s)

Confirmed or suspected maternal infection within 6 weeks of delivery.

Key secondary outcome(s)

1. Need for additional perineal care/breast feeding determined within 6 weeks of delivery
2. Hospital admissions and diagnoses measured at one-year post delivery
3. Hospital bed stay/hospital and GP visits/wound breakdown/antibiotic side effects determined within 6 weeks of delivery
4. Maternal general health determined within 6 weeks of delivery
5. Relief/dyspareunia/ability to sit comfortably to feed the baby determined within 6 weeks of delivery
6. Perineal wound infection determined within 6 weeks of delivery
7. Cases of surgical site infection (perineal) determined within 6 weeks of delivery
8. Cases of systemic sepsis determined within 6 weeks of delivery

Completion date

31/01/2019

Eligibility

Key inclusion criteria

1. Female aged 16 years or over
2. Mental capacity (ability to give informed consent)
3. Have had an operative vaginal delivery at at least 36 weeks gestation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Total final enrolment

3427

Key exclusion criteria

Current exclusion criteria as of 04/05/2018:

1. Clinical indication for ongoing antibiotic administration post-delivery e.g. due to confirmed antenatal infection, 3rd or 4th degree tears. Note that receiving antenatal antibiotics e.g. for maternal Group B Streptococcal carriage or prolonged rupture of membranes, is not a reason for exclusion if there is no indication for ongoing antibiotic prescription post-delivery.
2. Known allergy to penicillin or to any of the components of co-amoxiclav, as documented in hospital notes.
3. History of anaphylaxis (a severe hypersensitivity reaction) to another β -lactam agent (e.g. cephalosporin, carbapenem or monobactam), as documented in hospital notes.

Previous exclusion criteria:

1. Clinical indication for ongoing antibiotic administration post-delivery (e.g. due to confirmed antenatal infection, third or fourth degree tears)
2. Known allergy to penicillin (as documented in hospital notes)

Date of first enrolment

29/02/2016

Date of final enrolment

13/06/2018

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre**NPEU Clinical Trials Unit**

National Perinatal Epidemiology Unit (NPEU)

University of Oxford

Old Road Campus

Headington
United Kingdom
OX3 7LF

Sponsor information

Organisation

University of Oxford

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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	15/06/2019	20/05/2019	Yes	No
Results article	results	01/10/2019	10/10/2019	Yes	No
Protocol article	protocol	24/07/2018		Yes	No
HRA research summary			28/06/2023	No	No