ISRCTN11166984 https://doi.org/10.1186/ISRCTN11166984

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

Submission date
23/09/2015

Registration date
23/09/2015

Last Edited
10/10/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Contact information

Type(s)
Public

Contact name
Ms Nelly Owino

Contact details
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Additional identifiers

EudraCT/CTIS number
2015-000872-89

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 amoxycillin/200mg clavulanic acid in 20ml water for injections for active drug, 20ml 0.9% saline for placebo)

Intervention Type
Other

Primary outcome measure
Confirmed or suspected maternal infection within 6 weeks of delivery.

Secondary outcome measures
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

Overall study start date
01/09/2015

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

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 3424; UK Sample Size: 3424

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
England

United Kingdom

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

Sponsor details
Nuffield Department of Obstetrics & Gynaecology
Level 3
Women's Centre
John Radcliffe Hospital
Oxford
England
United Kingdom
OX3 9DU

Sponsor type
Hospital/treatment centre

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

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

Intention to publish date
30/06/2019

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