

Azithromycin for the treatment of pelvic inflammatory disease (PID)

Submission date 25/02/2014	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 25/02/2014	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 06/04/2021	Condition category Urological and Genital Diseases	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Pelvic inflammatory disease (PID) is caused by the spread of sexually transmitted infections from the vagina and cervix. If inadequately treated, PID can have serious consequences such as scarring of the fallopian tubes, which can lead to infertility, ectopic pregnancy and chronic pelvic pain. If taken correctly, a standard 14 days of antibiotic treatment has a cure rate of over 90%. However, because symptoms often improve within 7 days and antibiotics cause significant side effects, many women stop taking the medication early, thus the infection may not clear completely and may lead to further complications. The aim of this study is to simplify the standard antibiotic treatment for pelvic inflammatory disease (PID).

Who can participate?

Women who attend the genitourinary clinic with mild to moderate symptoms of PID (pain for less than 30 days)

What does the study involve?

Women are examined, have swabs taken to check for infection and are asked to fill in a questionnaire about pain and their beliefs around medicines. Women are then randomly allocated to either the standard of care (14 days of antibiotics) or the 5-day course of antibiotics. The women and research nurse know which antibiotics they are taking, but not the doctor. At follow-up in the clinic women are asked to complete a further questionnaire about pain, health beliefs, side effects and ability to take the tablets. The research nurse calls the women at 68 weeks for a final assessment, and where infection was found, invites women for repeat samples.

What are the possible benefits and risks of participating?

If a difference is found between the two antibiotic regimens in women with PID it will change the local treatment policies and so may improve future treatments for patients. There are no risks from any of the antibiotics; they are all used commonly for other conditions. All antibiotics can sometimes cause nausea, vomiting and rash but participants may not experience any side effects at all.

Where is the study run from?

This is a multi-centre study running in Brighton, London, Birmingham, Eastbourne/Hastings and Sheffield (UK).

When is the study starting and how long is it expected to run for?

November 2012 to May 2015

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Dr Gillian Dean, gillian.dean2@nhs.net

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

2010-023254-36

Protocol serial number

11656

Study information

Scientific Title

Is a short course of azithromycin effective in the treatment of mild to moderate pelvic inflammatory disease (PID)?

Study objectives

The aim of this study is to assess whether a shorter course of antibiotics taken over 5 days is as effective as the 14 day course and whether women find the shorter course more acceptable when compared to the current standard of treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee South East Coast - Brighton and Sussex, 10/03/2011, ref.:10/H1107/70

Primary study design

Interventional

Study design

Randomised; Interventional; Design type: Treatment

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Infection, Reproductive Health and Childb; Subtopic: Infection (all Subtopics), Reproductive Health and Childb (all Subtopics); Disease: Infectious diseases and microbiology , Reproductive Health & Childbirth

Interventions

Standard of care (14 days of antibiotics) or the 5 day course of antibiotics.

Abdominal & Bimanual Exam, Modified McCormack Score used.

Baseline and Day 14-21; BMQ questionnaire

Baseline and Day 14-21; Informed Consent, Informed consent in writing before any protocol specific procedures

MARS Questionnaire, Day 14-21 visit

Side Effects Questionnaire, Day 14-21 visit

Telephone follow-up, 6-8 week follow-up visit

Urinalysis, Baseline for pregnancy test

Visual Analogue Scale for Pain, At Baseline and Day 14-21 visit

Follow-Up Length: 2 month(s)

Study Entry: Single Randomisation only

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Azithromycin

Primary outcome(s)

Clinical efficacy of treatment regimes; Timepoint(s): Comparing improvement of pain scores: baseline to Day 14-21

Key secondary outcome(s)

1. Comparison of adherence; Timepoint(s): Day 14-21
2. Comparison of costs; Timepoint(s): 3 month notes review
3. Comparison of side effects; Timepoint(s): Day 14-21
4. Microbiological cure when organisms identified; Timepoint(s): Day 14-21 and 6-8 week follow-up
5. Mycoplasma anti-microbial resistance; Timepoint(s): Day 14-21 and 6-8 week follow-up
6. Prevalence of causative organisms in study population; Timepoint(s): Day 14-21

Completion date

01/05/2015

Eligibility

Key inclusion criteria

Presence of all of:

1. Pelvic discomfort for < 30 days
2. Direct lower abdominal tenderness +/- rebound tenderness
3. Adnexal/cervical motion tenderness
4. Target Gender: Female; Upper Age Limit 60 years ; Lower Age Limit 16 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Total final enrolment

313

Key exclusion criteria

1. Women who do not consent
2. Age < 16 years
3. Abdominal pain requiring hospital admission
4. Positive pregnancy test
5. Urinary tract infection
6. Temperature >38 °C (indicator of severe infection)
7. Antibiotics within the last 7 days
8. Known allergy or intolerance to antibiotic component
9. Ultrasound scan showing other pathology
10. History of epilepsy
11. Severe depression

Date of first enrolment

01/11/2011

Date of final enrolment

01/09/2015

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Royal Sussex County Hospital

Brighton

United Kingdom

BN2 5BE

Sponsor information

Organisation

Brighton and Sussex University Hospitals NHS Trust (UK)

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (UK) - Research for Patient Benefit (RfPB); Grant Codes: PB-PG-0609-19279

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

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/11/2020	06/04/2021	Yes	No
HRA research summary			28/06/2023	No	No