# Azithromycin for the treatment of pelvic inflammatory disease (PID)

Recruitment status  No longer recruiting	Prospectively registered		
	☐ Protocol		
Overall study status Completed	Statistical analysis plan		
	[X] Results		
Condition category	[] Individual participant data		
	No longer recruiting  Overall study status  Completed		

# 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

Dr Gillian Dean

#### Contact details

Royal Sussex County Hospital Eastern Road Brighton United Kingdom BN2 5BE

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# Additional identifiers

**EudraCT/CTIS number** 2010-023254-36

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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

## Study design

Randomised; Interventional; Design type: Treatment

## Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

## Participant information sheet

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

# 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 measure

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

## Secondary outcome measures

- 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

## Overall study start date

02/11/2012

# 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** 

#### Age group

Adult

#### Sex

**Female** 

# Target number of participants

Planned Sample Size: 396; UK Sample Size: 396

#### Total final enrolment

### 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

England

**United Kingdom** 

# Study participating centre Royal Sussex County Hospital

Brighton United Kingdom BN2 5BE

# Sponsor information

# Organisation

Brighton and Sussex University Hospitals NHS Trust (UK)

#### Sponsor details

Mr Scott Harfield Royal Sussex County Hospital Eastern Road Brighton England United Kingdom BN2 5BE

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# Sponsor type

Hospital/treatment centre

# 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**

# Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

# Intention to publish date

# 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