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Azithromycin for the treatment of pelvic inflammatory disease (PID)

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

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

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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

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
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)

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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