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Gentamicin in the treatment of Gonorrhoea (G-TOG)

Submission date	Recruitment status	[X] Prospectively registered
18/09/2014	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/09/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/12/2021	Infections and Infestations	

Plain English summary of protocol

Background and study aims
Currently the antibiotic ceftriaxone is used to treat gonorrhoea but there is increasing evidence that this antibiotic is becoming less effective over time and will stop curing patients with gonorrhoea within the next few years. Many currently available antibiotics do not work against gonorrhoea and there is an urgent need to find an alternative treatment which is effective and safe. Gentamicin which is an existing antibiotic, might be effective against gonorrhoea. Testing in the laboratory suggests that gentamicin could be used to treat gonorrhoea, and it has been used as a treatment in some developing countries with success. A review looking for previously published studies which assessed gentamicin found that the existing trials are of low quality and that there are no recent clinical trials. Therefore a randomised study to compare the efficacy of ceftriaxone and gentamicin has been designed. This will assess whether gentamicin is a safe and effective treatment for gonorrhoea.

Who can participate?
Patients diagnosed with gonorrhoea infection will be asked to join the study

What does the study involve?
and be randomised to receive either gentamicin or ceftriaxone. Both are given by injection. All patients will also receive azithromycin which is currently given in combination with ceftriaxone in the treatment of gonorrhoea. Patients will be asked to come back to clinic 2 weeks after their treatment to be tested to see if their gonorrhoea has cleared. The safety of both antibiotics will also be assessed.

What are the possible benefits and risks of participating?
There are no direct benefits for the participant of taking part in the study. However, the information we get from this study will help us to see if gentamicin is as good as ceftriaxone. This could benefit patients with gonorrhoea in the future. Although previous studies suggest that it is effective, there is a risk that gentamicin may not work as well as ceftriaxone and that participants may have to have further treatment. There is also a risk of side effects from both antibiotics, although we think this risk is low as they are only given once. Ceftriaxone can cause diarrhoea, anaemia, abnormalities in white blood cells and problems with kidney and liver function. Gentamicin can cause problems with hearing, balance and kidney function.

Where is the study run from?
Notitngham Clinical Trials Unit, UK

When is the study starting and how long is it expected to run for?
October 2014 to December 2016

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

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2014-001823-56

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
17433; HTA 12/127/10

Study information

Scientific Title
A randomised controlled trial to compare the clinical effectiveness and safety of gentamicin and ceftriaxone in the treatment of gonorrhoea

Acronym
G-TOG

Study objectives
The study is to trying to find out whether gentamicin is an acceptable alternative to ceftriaxone, in the treatment of gonorrhoea. This will be done by determining whether the clearance rate of gonorrheoa in participants receiving gentamicin is no worse than the rate in participants receiving ceftriaxone. In parallel, the safety of both treatments will be assessed.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/1212710

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central - Oxford C REC; ref: 14/SC/1030

Study design
Randomised; Interventional; Design type: Not specified

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: Infectious diseases and microbiology; Subtopic: Infection (all Subtopics); Disease: Infectious diseases and microbiology

Interventions
Gentamicin (240 mg), Gentamicin (240 mg) vs Ceftriaxone (500 mg) for the treatment of gonorrhoea. Participants will be randomised to receive a single intramuscular injection of gentamicin (240 mg) or ceftriaxone (500 mg). All participants will also receive a single oral dose of azithromycin (1 g) as standard care.

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Gentamicin, ceftriaxone, azithromycin

Primary outcome measure
Clearance of N. gonorrhoeae at all the infected sites confirmed by a negative NAAT (Aptima Combo), two weeks post treatment (as recommended by the British Association for Sexual Health and HIV).

Secondary outcome measures
1. Clinical resolution of symptoms
2. Frequency of nausea/vomiting, hearing loss, dizziness and rash
3. Frequency of other adverse events
4. Tolerability of therapy
5. Relationship between clinical effectiveness and MIC to inhibit N. gonorrhoeae growth
6. Cost effectiveness

Overall study start date
01/10/2014

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Aged 16-70 years
2. Diagnosis of uncomplicated untreated genital, pharyngeal or rectal gonorrhoea based on a positive gram stained smear on microscopy, or positive NAAT
3. Written informed consent provided

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 720; UK Sample Size: 720

Total final enrolment
720

Key exclusion criteria
1. Known concurrent bacterial sexually transmitted infection (apart from chlamydia)
2. Known contraindications or allergy to gentamicin, ceftriaxone, azithromycin or lidocaine

3. Pregnant or breastfeeding
4. Current clinical diagnosis of complicated gonorrhoea infections eg pelvic inflammatory disease, epididymoorchitis
5. Weight less than 40kg at the time of randomisation
6. Currently receiving or have received ceftriaxone or gentamicin within the preceding 28 days
7. Previous participation in this study

Date of first enrolment
01/10/2014

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queens Medical Centre
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University Hospital Birmingham NHS Foundation Trust (UK)

Sponsor details
Birmingham & Black Country
Research and Development
Queen Elizabeth Hospital
Edgbaston
Birmingham
England
United Kingdom
B15 2TH

Sponsor type
Hospital/treatment centre

ROR

https://ror.org/014ja3n03

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
31/03/2019

Individual participant data (IPD) sharing plan
The datasets analysed during the current study will be available upon request from the NCTU (ctu@nottingham.ac.uk), a minimum of 6 months after publication of the main results paper. Access to the data will be subject to review of a data sharing and use request by a committee including the CI and sponsor, and will only be granted upon receipt of a data sharing and use agreement. Any data shared will be pseudo anonymised which may impact on the reproducibility of published analyses.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	24/11/2016		Yes	No

Results article	results	22/06/2019	08/05/2019	Yes	No
Results article	results	01/05/2019	20/05/2019	Yes	No
Results article	results	01/12/2020	03/08/2020	Yes	No
Results article		22/08/2020	15/12/2021	Yes	No