

Gentamicin in the treatment of Gonorrhoea (G-TOG)

Submission date 18/09/2014	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 18/09/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/12/2021	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

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?
Nottingham 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

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Additional identifiers

Clinical Trials Information System (CTIS)
2014-001823-56

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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 try 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 gonorrhoea 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

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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, epididymo-orchitis
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

United Kingdom

England

Study participating centre

Queens Medical Centre

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

University Hospital Birmingham NHS Foundation Trust (UK)

ROR

<https://ror.org/014ja3n03>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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?
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
Protocol article	protocol	24/11/2016		Yes	No