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Dequalinium versus usual care antibiotics for the treatment of bacterial vaginosis

Submission date
09/01/2020

Recruitment status
No longer recruiting

Registration date
20/01/2020

Overall study status
Completed

Last Edited
12/02/2025

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Bacterial vaginosis (BV) causes a vaginal discharge that has an unpleasant smell. It is the most common cause of discharge and up to a third of women will get it at some time in their lives. We do not know why BV occurs but there is a change in the balance of the vaginal bacteria with a reduction in the 'good' bacteria that protect against infections and an increase in many other bacteria. Current treatments often do not not cure BV completely, but treating BV is important as the symptoms are unpleasant. Also, it can cause miscarriage, premature birth and it increases the risk of catching HIV and other sexually transmitted infections.
Oral or vaginal antibiotics are recommended for treating BV. These can cause side effects such as dizziness, nausea and vaginal soreness. Over 1 in 5 women get BV back within one month of treatment and have to take repeated courses of antibiotics. Concern about bacteria becoming resistant to antibiotics and damage to the body's good bacteria means that non-antibiotic therapies are being considered for BV.
There is a new treatment available for BV called dequalinium which works as a vaginal antiseptic. Its potential advantages are that it will not damage the good bacteria throughout the body or cause antibiotic resistance. Two studies have suggested that it could be effective and safe but the number of women included were small so the results were not conclusive. Also, dequalinium is more expensive than some of the usual care antibiotics. The aim of this study is to see if dequalinium is as good at treating BV as current BV antibiotics.

Who can participate?
Women from the UK with a diagnosis of bacterial vaginosis.

Added 11/05/2021:
Women can screen for the trial via one of three recruitment pathways:

Pathway 1 – face-to-face recruitment via a GUM clinic
Patients attending clinic appointments and being seen in person at a clinic consultation will be identified and recruited by a participating GUM clinic. Participants in this pathway will be screened, consented and randomised during their clinical consultation by a member of the site

DEVA research team. Participants will be issued their study medication during their consultation and will not be required to provide additional vaginal samples or attend further clinic visits as part of their trial participation.

Pathway 2 – remote recruitment via a GUM clinic
In light of the COVID-19 pandemic, face-to-face appointments may not always be conducted. It is expected that routine clinic appointments may be carried out remotely via telephone/video call in place of an in-clinic visit. Patients with suspected BV will be identified and recruited by the participating GUM clinic, however, the trial will be discussed during a remote consultation (telephone or video) with a member of the site DEVA research team and the Participant Information Sheet (PIS) and Informed Consent Form (ICF) will be provided electronically.
In order to confirm eligibility for the trial, consented patients will be required to take a self-taken vaginal swab to confirm a BV diagnosis. Patients will be posted a trial sample kit containing two swabs; one to confirm their BV diagnosis and the other for STI screening (this is for the purpose of the trial only and will only be tested if it is confirmed that they have BV and are randomised onto the trial). Patients with a positive BV microscopy result, who remain interested in participating will complete final eligibility and be randomised onto the trial. Trial medication will be prescribed and dispensed directly from the recruiting site to participants in accordance with local policy. Those who do not have BV on microscopy will be informed that they are ineligible for the trial because their symptoms are not due to BV so BV treatment will not be of benefit to them. They will be advised to contact their GP or local sexual health clinic if their symptoms persist.

Pathway 3 – self-referral via the DEVA trial website
Patients can express their interest in joining the trial via a self-referral (pre-screen) form on the trial website. Those patients who meet the pre-screen criteria will complete a web form with their personal details and on submission of this the LSH DEVA research team, who will manage the care of all participants who are recruited via this pathway, will be notified to contact them to discuss the trial. Those who remain interested in participating will be sent a link with their PIS and ICF electronically.
In order to confirm eligibility for the trial, consented patients will be required to take a self-taken vaginal swab to confirm a BV diagnosis. Patients will be posted a trial sample kit containing two swabs; one to confirm their BV diagnosis and the other for STI screening (this is for the purpose of the trial only and will only be tested if it is confirmed that they have BV and are randomised onto the trial). Patients with a positive BV microscopy result, who remain interested in participating will complete final eligibility and be randomised onto the trial. Trial medication will be prescribed and dispensed directly from the recruiting site to participants in accordance with local policy. Those who do not have BV on microscopy will be informed that they are ineligible for the trial because their symptoms are not due to BV so BV treatment will not be of benefit to them. They will be advised to contact their GP or local sexual health clinic if their symptoms persist.

What does the study involve?
Participants will be assigned to treatment groups using a remote internet-based randomization system to one of the following the intervention or control arm.

The intervention arm will receive dequalinium chloride 10 mg vaginal tablet for 6 nights. This is the formulation and course that is licensed for use in the UK.

The control arm will receive usual care antibiotics. Clinician-chosen usual care antibiotic treatment selected from UK guideline-recommended or alternative oral or topical antibiotic BV treatments which (at the time of writing the protocol) will be one of the following treatments:

1. Metronidazole 400 mg orally twice daily for 5-7 days
2. Metronidazole 2 g single dose orally
3. Intravaginal metronidazole gel (0.75%) once daily for 5 days
4. Intravaginal clindamycin cream (2%) once daily for 7 days
5. Tinidazole 2 g single dose orally
6. Clindamycin 300 mg orally twice daily for 7 days

Women who screen and recruit via pathways 2 and 3 will be asked to take their vaginal samples at home, 4 weeks after they start their treatment. These samples will be used to assess for clinical diagnosis of bacterial vaginosis. A subgroup of women in each arm, who provide additional informed consent will take additional vaginal samples at baseline/eligibility and week 4 for future research into vaginal microbiota. This sub-study is only available to women participating in pathways 2 and 3 and will be stopped once 150 sample pairs have been received.

All participants will be sent confidential online questionnaires at 4 weeks and 12 weeks to ask about if symptoms have cleared, the amount of treatment used, the side effects and the acceptability of the treatment

What are the possible benefits and risks of participating?
Although you may not receive any immediate extra benefit from taking part, this research will help to improve the treatments and care provided to all women with BV in the future. If the study shows that dequalinium chloride is as good as antibiotics in treating BV, it may also result in fewer antibiotics being used which would be a benefit to society as a whole.

As a thank you to the women who complete each questionnaire, they will receive a £10 Amazon voucher (£20 in total). When they complete their 12-week questionnaire they will be entered into a free prize draw for a chance to receive a £100 Amazon voucher. The winner will be selected randomly after the last questionnaire has been received and will be notified by email which will contain their prize.

Dequalinium chloride is already used to treat episodes of BV, we still do not know if it works as well as current antibiotics. If it does not work as well, participants may need to take additional treatment to treat their BV. As with all medications, there is a small risk of side effects and with dequalinium chloride, this may include vaginal candidiasis (thrush/yeast infection) and vulvovaginal discomforts such as itching and/or burning sensations. For those who are randomised to receive usual care antibiotics the side effects of those medications will be explained to the participant by the research team.

Where is the study run from?
The study is being run from Leeds Teaching Hospital NHS Trust (Genitourinary Medicine, George Street, Leeds, LS1 3EX) and 14 other participating sexual health clinics (to be decided).

When is the study starting and how long is it expected to run for?
August 2019 to April 2025

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

Who is the main contact?
Mr Mickey Lewis, deva@nottingham.ac.uk

Study website

https://www.devastudy.ac.uk/

Contact information

Type(s)
Public

Contact name
Mr Mickey Lewis

Contact details
Applied Health Research Building
University Park
University of Nottingham
Nottingham
United Kingdom
NG7 2UH
01157487105
deva@nottingham.ac.uk

Additional identifiers

EudraCT/CTIS number
2019-002819-25

IRAS number
269405

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
GU18/108645, IRAS 269405

Study information

Scientific Title
DEqualinium versus usual care antibiotics for the treatment of bacterial VAginosis (DEVA): a multicentre randomised, open label, non-inferiority trial

Acronym
DEVA

Study objectives
Current study hypothesis as of 11/05/2021:
To determine if dequalinium chloride is effective in the management of bacterial vaginosis (BV) compared to usual care antibiotics without the need for additional treatment.

Previous study hypothesis:
To determine if dequalinium chloride is effective in the management of bacterial vaginosis (BV) compared to usual care antibiotics.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/04/2020, North West - Liverpool Central Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8197, +44 (0) 2071048387, +44 (0)207 104 8056; liverpoolcentral.rec@hra.nhs.uk), REC ref: 20/NW/0113

Study design
Multi-centre randomized open-label parallel-group non-inferiority trial with equal allocation (1:1)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not yet available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Bacterial vaginosis

Interventions
Participants will be assigned to treatment groups using a remote internet-based randomization system to one of the following the intervention or control arm.

The intervention arm will receive dequalinium chloride 10mg vaginal tablet for 6 nights. This is the formulation and course that is licensed for use in the UK.

The control arm will receive usual care antibiotics. Clinician-chosen usual care antibiotic treatment selected from UK guideline recommended or alternative oral or topical antibiotic BV treatments which (at the time of writing the protocol) will be one of the following treatments:
1. Metronidazole 400 mg orally twice daily for 5-7 days
2. Metronidazole 2 g single dose orally
3. Intravaginal metronidazole gel (0.75%) once daily for 5 days
4. Intravaginal clindamycin cream (2%) once daily for 7 days
5. Tinidazole 2 g single dose orally
6. Clindamycin 300 mg orally twice daily for 7 days

A subgroup of women in each arm, who provide informed consent to take their own vaginal swabs at home and post them to us at 4 weeks, will also be assessed for clinical diagnosis of bacterial vaginosis.

For both arms, participants will be sent confidential online questionnaires at 4 weeks and 12 weeks to ask about if symptoms have cleared, the amount of treatment used, the side effects and the acceptability of the treatment

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Dequalinium chloride, usual care antibiotics

Primary outcome measure
Participant-reported resolution of bacterial vaginosis (BV) symptoms without the need for additional treatment assessed by online questionnaire at 4 weeks.

Secondary outcome measures
1. Participant-reported resolution of bacterial vaginosis (BV) symptoms (with or without the need for additional treatment) assessed by online questionnaire at 4 weeks
2. Time to participant-reported resolution of BV symptoms without the need for additional treatment assessed by online questionnaire at 4 weeks
3. Microscopic resolution of BV (without the need for additional treatment) on microscopy at 4 weeks as assessed by central laboratory analysis of participant-taken vaginal smears (in a subgroup of participants)
4. Participant reported proportion of prescribed trial BV treatment taken assessed by online questionnaire at 4 weeks
5. Participant-reports of vaginal irritation (itching, pain and/or burning), vaginal discharge, unpleasant vaginal smell, nausea, vomiting, diarrhoea, abdominal pain, unpleasant taste and candida infection assessed by online questionnaire at 4 weeks and 12 weeks
6. Participant-reported acceptability of /satisfaction with treatment assessed by online questionnaire at 4 weeks
7. Participant-reported recurrence of BV symptoms assessed by online questionnaire at 12 weeks
8. Time to participant reported recurrence of BV symptoms assessed by online questionnaire at 12 weeks
9. Cost of BV treatment, including additional medication and healthcare usage relating to BV assessed by online questionnaire at 4 weeks and 12 weeks

Overall study start date
01/08/2019

Completion date
14/04/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 06/10/2023:

1. People with a vagina (assigned female at birth) aged 16 years and over
2. Diagnosis of BV confirmed by microscopy with symptoms of vaginal odour plus or minus vaginal discharge requiring treatment with usual care (BV guideline recommended) antibiotics
3. Willing to use either intravaginal dequalinium chloride tablets (pessaries) or the clinician selected usual care antibiotic BV treatment
4. Willing to avoid vaginal sex whilst taking/using trial treatment
5. Willing to avoid vaginal douching whilst taking/using trial treatment
6. Willing to complete follow up

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Previous inclusion criteria:

1. Cisgender women aged 16 years and over
2. Diagnosis of BV confirmed by on-site microscopy (Ison-Hay Grade 3) with symptoms of vaginal odour plus or minus vaginal discharge requiring treatment with usual care (BV guideline recommended) antibiotics
3. Willing to use either intravaginal dequalinium chloride tablets (pessaries) or the clinician selected usual care antibiotic BV treatment
4. Willing to avoid vaginal sex whilst taking/using trial treatment
5. Willing to avoid vaginal douching whilst taking/using trial treatment
6. Willing to complete follow up questionnaires in English
7. Written informed consent to participation given

Participant type(s)
Patient

Age group
Mixed

Lower age limit
16 Years

Sex
Female

Target number of participants
1316

Total final enrolment
1313

Key exclusion criteria
Current exclusion criteria as of 06/10/2023:

1. Contra-indications or allergy to dequalinium chloride or clinician selected usual care antibiotic BV treatment
2. Use of antibiotics concurrently, within the 14 days prior to randomisation or planned use over

the 14 days from randomisation
3. Use of intravaginal therapies (including vaginal douching) concurrently, within the 14 days prior to randomisation or planned use over the 14 days from randomisation
4. Pregnant females who are seeking a termination
5. Unwilling to provide GP information (only to be used for pregnant females or females who become pregnant in the first 4 weeks of the trial)
6. Current use of gender affirming hormones (androgens and anti-oestrogens)
7. Previous participation in this trial
8. Resident outside the UK (for shipment of trial medication and sample kits only)

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Previous exclusion criteria:

1. Contra-indications or allergy to dequalinium chloride or clinician selected usual care antibiotic bacterial vaginosis (BV) treatment
2. Concurrent use of oral antibiotics, within the past 14 days or planned use over the next 14 days
3. Concurrent use of intravaginal therapies (including vaginal douching), within the past 14 days or planned use over the next 14 days
4. Diagnosis of any infection at the baseline visit that requires immediate antibiotic treatment
5. Pregnant women who are seeking a termination
6. Pregnant women or women who become pregnant in the first 4 weeks of the trial who are unwilling to provide GP information
7. Previous participation in this trial

Added 11/05/2021:
8. Resident outside the UK (for shipment of trial medication and sample kits only)

Date of first enrolment
20/08/2021

Date of final enrolment
20/12/2024

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Leeds Teaching Hospital NHS Trust
Genitourinary Medicine
George Street

Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Leeds Teaching Hospitals NHS Trust

Sponsor details
Research and Innovation Centre
Leeds Teaching Hospitals NHS Trust
St James's University Hospital
Beckett Street
Leeds
England
United Kingdom
LS9 3EX
+44 01132060454
leedsth-tr.researchgovernance@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.leedsth.nhs.uk/home/

ROR
https://ror.org/00v4dac24

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

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
The dissemination of the proposed research findings will be via a published HTA monograph, research papers for publication in peer-reviewed journals, presentation at medical conferences and communication of our findings to groups involved in guideline development.

Results of this trial will be submitted for publication in a peer-reviewed journal.

Intention to publish date
30/11/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from CTU-admin@nottingham.ac.uk

Updated 26/02/2020:
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 pseudoanonymised 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		21/12/2022	27/01/2023	Yes	No
HRA research summary			28/06/2023	No	No