ISRCTN14352909 https://doi.org/10.1186/ISRCTN14352909

Tampons for sexually transmitted infection (STI), bacterial vaginosis (BV) and human papillomavirus (HPV) screening

Submission date
02/01/2024

Recruitment status
No longer recruiting

Registration date
02/01/2024

Overall study status
Completed

Last Edited
23/07/2025

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
The purpose of this study is to find out whether the DAYE Diagnostic Tampon (DDT) can be used to find out if you have a range of common vaginal infections (HPV, BV, chlamydia and gonorrhoea). It will also compare the DDT to using a standard vaginal swab (self-swab and a swab taken by a female clinician). The trial aims to understand how acceptable using a tampon for this type of testing is for women, what potential barriers there are to using tampons in this way, and how easy they find the tampon to use. It is hoped that by incorporating diagnostic testing into a tampon, more women could find out about infections and get appropriate treatment faster than the way things are done at the moment. The trial aims to recruit 350 women from the UK and Italy, of which 50 will have recently tested positive for HPV.

Who can participate?
We are inviting individuals assigned female at birth, aged 25-65 years, who are sexually active (defined as having penetrative vaginal sex) to participate in this study. Some people invited to the study will already have been recently diagnosed with HPV (based on a recent test). A member of the trial team will check whether you are suitable for the study based on the study eligibility criteria and the data you provide.

What does the study involve?
After consenting to take part in the study and providing some information about yourself and your medical history you will have three types of sample taken. The DDT will be provided to you by your Doctor or sent directly to you via post to be administered at home. You should use the DDT and self-swab the day before your study visit and bring both samples with you to give to the study nurse or medically qualified healthcare professional in the packaging provided. You will be randomly assigned to a group which will determine the order you take the at-home samples.

The study will be conducted with one or two in-person visits. At the visit(s) a study nurse or medically qualified healthcare professional will perform a vaginal swab. You may be given the DDT at a clinic visit, or it may be sent to you at home in advance of a visit. Detailed instructions will be provided with the DDT and self-swab kit for how to use the DDT and self-swab, which

order to take the samples in, and how to package and store the samples before your visit. Your Doctor will let you know how many visits your trial participation will include.

At the beginning of the study, and after the samples are taken you will be asked to complete questionnaires about your experiences. You will either receive a link to complete the questionnaires, using your smartphone, tablet or computer, or you may complete the questionnaires on paper at a clinic visit.

(UK only): You will be asked to provide details of your GP and they will be informed about your participation in this study, and if you consent they will also be informed about any positive results of tests done on the samples taken.

What are the possible benefits and risks of participating?
You will not benefit directly from taking part in this study, but the results of this trial may result in women having access to an easier, more convenient method of testing for HPV, BV and chlamydia and gonorrhoea in the future.

No significant risks are anticipated, as the DDT and the other sampling methods are not expected to cause any side effects. If you do experience any untoward events or symptoms you should report these to the trial team and your Doctor. You should ensure you only wear the DDT for the time indicated in the instruction booklet, and for no longer than 4 hours to minimise the rare risk of Toxic Shock Syndrome (TSS). TSS is a rare but serious condition that can occur when certain bacteria produce harmful toxins in your body. It can be associated with tampon use and can lead to symptoms like high fever, low blood pressure, a rash, and problems with organs like the liver and kidneys. If not treated promptly, it can be life-threatening. It's crucial to be aware of the symptoms, especially when using tampons, and seek medical help if you suspect TSS. Completing the questionnaires will take time, but these have been designed to be as short as possible and easy to access online.

Where is the study run from?
The study is being run by Lindus Health (UK) on behalf of the sponsor Tampon Innovations Ltd, a subsidiary of Daye (Bulgaria)

When is the study starting and how long is it expected to run for?
July 2023 to July 2025

Who is funding the study?
The study is funded by Tampon Innovations Ltd, a subsidiary of Daye (Bulgaria)

Who is the main contact?
STAMP@lindushealth.com

Contact information

Type(s)
Scientific, Principal investigator

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Public

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT06154239

Integrated Research Application System (IRAS)
334064

Central Portfolio Management System (CPMS)
58535

Protocol serial number
LH-DA-01.

Study information

Scientific Title
Screening with tampons: evaluating diagnostic accuracy for STIs, BV and HPV and assessing participant views

Acronym
STAMP

Study objectives
Vaginal health screening often has very low uptake, meaning that most women are unaware of their HPV, BV and STI status. Knowledge of HPV status could encourage uptake of preventative treatments (such as HPV vaccine) and uptake of screening for cervical cancer. Cervical cancer is

one of the most preventable and curable forms of cancer as long as it is detected early and managed effectively. The Daye Diagnostic Tampon offers a preferred sampling method for screening which will help improve uptake of testing and enable timely diagnosis and treatment.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/12/2023, London - Camberwell St Giles REC (Whitefriars Lewins Mead, Bristol, BS1 2NT, United Kingdom; +44 207 104 8138; camberwellstgiles.rec@hra.nhs.uk), ref: 23/LO/0882

Primary study design
Observational

Study design
Diagnostic trial comparing the diagnostic accuracy of the DAYE Diagnostic Tampon (DDT) with a vaginal swab (self-collected and clinician taken)

Study type(s)
Diagnostic, Screening

Health condition(s) or problem(s) studied
Chlamydia, gonorrhea, bacterial vaginosis (BV) and human papillomavirus (HPV)

Interventions
Current interventions as of 11/09/2024:
All participants in the main study will have 3 samples taken: DAYE Diagnostic Tampon (DDT), self-swab and clinician-administered swab. All participants in the sub-study will have 2 samples taken: Daye Diagnostic Tampon (DDT) and self-swab.

All participants will be randomised into 2 groups for sampling order between the DDT and self-swab.

Previous interventions:
All participants will have 3 samples taken: DAYE Diagnostic Tampon (DDT), self-swab and clinician-administered swab. Participants will be randomised into 2 groups for sampling order between the DDT and self-swab.

All participants will be randomised according to sample order for the DDT and self-swab using block randomisation. Randomisation will be performed at the point of enrolment by a member of the trial team using a pre-generated list of treatment allocation blocks provided by the study statistician.
Group A: Approximately half the participants will perform the self-swab followed by the DDT.
Group B: Approximately half the participants will perform the DDT followed by the self-swab.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Assays run on each swab:
1. Hologic’s APTIMA HPV (for HPV)

2. Hologic's APTIMA AC (for chlamydia and gonorrhoea)
3. Cepheid MPV assay (for BV)

DDT and self-swab are taken at clinic visit minus 24 hours
Clinician swab is taken at the clinic visit
Assays are run within 4 weeks of receipt of samples at the laboratory

Key secondary outcome(s)

Current secondary outcome measures as of 11/09/2024:
1. Assess the usability of the DDT via After-Scenario Questionnaire (ASQ) collected in the post-sampling questionnaire. Higher ASQ scores = more usable.
2. Explore participants views of the usability and acceptability of the DDT using quantitative and qualitative feedback from pre- and post-sampling questionnaires
3. Explore participants views of the usability and acceptability of the DDT using qualitative feedback from focus groups after study completion
4. Assess whether the DDT is a preferred sampling method for participants via user preferences (self-report) in the Pre-sampling (baseline) and Post-sampling (once all samples are collected) questionnaires.
5. Assess if the order of sample collection (self-swab vs DDT) impacts diagnostic accuracy as assessed by assays via a comparison between the detection accuracy of infections between sample order (Group A and Group B).
6. Willingness to pay for the DDT via questions in post-sampling questionnaire.
7. Understand the health economic consequences of using the DDT for STI, BV and HPV testing via a comparison of time taken for DDT vs clinician swab as recorded by the participant in the post-sampling questionnaire.
8. Explore stakeholder attitudes to tampons as a means of sample collection for microbial testing via qualitative feedback from stakeholder questionnaires collected throughout the trial (and once stakeholders with a role in the trial have engaged with the tampon)
9. Assess the occurrence of AEs/SAEs as a result of tampon sampling via recording of AE/SAE occurrence throughout the trial.

Other Pre-specified Outcome Measures:
1. Explore the relationship between duration of wear of the DDT and diagnostic accuracy via assay compared with swabs (self and clinician taken).
Sub-study primary outcome:
1. Diagnostic accuracy of the STI testing using menstrual tampons compared to other specimen collection methods (self-swab) using the following assays: Hologic's APTIMA AC (for chlamydia and gonorrhoea)

Previous secondary outcome measures:
1. Assess the usability of the DDT via After-Scenario Questionnaire (ASQ) collected in the post-sampling questionnaire. Higher ASQ scores = more usable.
2. Explore participants views of the usability and acceptability of the DDT using quantitative and qualitative feedback from pre- and post-sampling questionnaires
3. Explore participants views of the usability and acceptability of the DDT using qualitative feedback from focus groups after study completion
4. Assess whether the DDT is a preferred sampling method for participants via user preferences (self-report) in the Pre-sampling (baseline) and Post-sampling (once all samples are collected) questionnaires.
5. Assess if the order of sample collection (self-swab vs DDT) impacts diagnostic accuracy as assessed by assays via a comparison between the detection accuracy of infections between sample order (Group A and Group B).

6. Willingness to pay for the DDT via questions in post-sampling questionnaire.
7. Understand the health economic consequences of using the DDT for STI, BV and HPV testing via a comparison of time taken for DDT vs clinician swab as recorded by the participant in the post-sampling questionnaire.
8. Explore stakeholder attitudes to tampons as a means of sample collection for microbial testing via qualitative feedback from stakeholder questionnaires collected throughout the trial (and once stakeholders with a role in the trial have engaged with the tampon)
9. Assess the occurrence of AEs/SAEs as a result of tampon sampling via recording of AE/SAE occurrence throughout the trial.

Other Pre-specified Outcome Measures:
1. Explore the relationship between duration of wear of the DDT and diagnostic accuracy via assay compared with swabs (self and clinician taken).

Completion date
17/07/2025

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 11/09/2024:
1. Individuals aged 25-65 years.
2. People assigned female at birth (AFAB).
3. Sexually active individuals. In this case, “sexually active” is defined as having penetrative vaginal sex.
4. Group 1 only: Confirmed HPV+ diagnosis within the past 4 weeks.
4.1. UK only: Ability to upload evidence of this diagnosis to the trial ePRO system (e.g. via a screenshot of the NHS app, or similar to be reviewed by the trial team).
5. Willingness to give informed consent and adhere to trial procedures.
6. Group 3 only (sub-study): A suspected or recently confirmed diagnosis of chlamydia or gonorrhoea (recently confirmed is a positive test within the last 5 days).

Previous participant inclusion criteria:
1. Individuals aged 25-65 years.
2. People assigned female at birth (AFAB).
3. Sexually active individuals. In this case, “sexually active” is defined as having penetrative vaginal sex.
4. Group 1 only: Confirmed HPV+ diagnosis within the past 4 weeks.
4.1. UK only: Ability to upload evidence of this diagnosis to the trial ePRO system (e.g. via a screenshot of the NHS app, or similar to be reviewed by the trial team).
5. Willingness to give informed consent and adhere to trial procedures.

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Other

Lower age limit
25 Years

Upper age limit
65 Years

Sex
Female

Total final enrolment
437

Key exclusion criteria
1. Previous hysterectomy or total hysterectomy with removal of cervix
2. Known allergy or sensitivity to tampons
3. History of TSS (both tampon-associated and non-tampon associated)
4. Individuals who are pregnant or breastfeeding.
5. Participation in another interventional clinical trial or use of investigational drugs in the last 30 days.
6. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial.

Date of first enrolment
08/01/2024

Date of final enrolment
17/07/2025

Locations

Countries of recruitment
United Kingdom

England

Italy

Study participating centre
Lindus Health
2nd Floor, 90 Union Street
London
United Kingdom
SE1 0NW

Sponsor information

Organisation
Tampon Innovations Ltd (a subsidiary of Daye)

Funder(s)

Funder type
Industry

Funder Name
Tampon Innovations Ltd

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 3.0	29/11/2023	02/01/2024	No	No
Protocol file	version 5.0	20/02/2024	11/03/2024	No	No
Protocol file	version 7.0	18/07/2024	11/09/2024	No	No
Statistical Analysis Plan	the SAP is included in section 8 version 3.0	29/11/2023	02/01/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes