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Exploring human papillomavirus and microbial environment in transgender and non-binary individuals with neovaginas

Submission date
13/05/2024

Recruitment status
No longer recruiting

Registration date
16/05/2024

Overall study status
Completed

Last Edited
03/12/2025

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
There is a good understanding of the viruses and bacteria (microbes) that reside in the vaginas of cisgender women. However, there is less understanding of the microbial environment within the constructed vaginas of transgender women post-gender affirmation surgery. Human papillomavirus (HPV), a common genital infection in cis individuals, is notably less understood in trans women. This study aims to find out if transgender women are willing to participate in research to help us understand more about the microbes that can reside in neovaginas and assess what kind of swab can be used in neovaginas to provide a good sample for testing in the laboratory. This work will serve to understand and improve neovaginal health in this population.

Who can participate?
Transgender or non-binary people aged 18 years and older (no upper age limit) who have had a vaginal construction procedure

What does the study involve?
This is a single centre, observational feasibility pilot study of 1-year duration that is targeting the recruitment of 20 participants. Participants will be asked to complete a questionnaire and provide two swabs from their neovagina.

What are the possible benefits and risks of participating?
There are no direct benefits that the participants will receive however they will be adding to the scientific knowledge of this area and, in turn, helping transgender individuals in the future. In terms of risks – there is a risk that some participants may find the sampling procedure uncomfortable however, the swabs are soft-tipped and have been used to support microbiological testing in the past so this risk is low.

Where is the study run from?
Royal Infirmary of Edinburgh, Scottish HPV Reference Laboratory

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

Who is funding the study?
1. The Chief Scientist Office
2. The University of Glasgow

Who is the main contact?
Dr Kate Cuschieri, kate.cuschieri@nhslothian.scot.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
341484

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 341484, UMON ED-001

Study information

Scientific Title
Understanding the human papillomavirus and microbial environment in transgender and non-binary people with neovaginas; a feasibility study

Acronym
UMON

Study objectives
This is a feasibility/pilot study so not powered. The main hypothesis is whether it is feasible to recruit transgender women into a study designed to assess HPV and microbial diversity in neovaginas through a gender identity clinic.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/06/2024, West Midlands - Solihull Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8191; solihull.rec@hra.nhs.uk), ref: 24/WM/0114

Submission pending

Study design
Single-centre feasibility pilot study

Primary study design
Observational

Study type(s)
Other, Prevention

Health condition(s) or problem(s) studied
Prevention of microbial disease in transgender women with neovaginas

Interventions
This is a single centre, observational feasibility pilot study of 1-year duration that is targeting the recruitment of 20 participants. There is no randomisation, participants will be asked to complete a questionnaire and provide two swabs from their neovagina.

Participants will be asked to provide two vaginal swabs, one self-taken and one taken by the clinician. They will also be asked to complete a brief questionnaire on vaginal hygiene procedures. Vaginal swabs will be sent to a central laboratory for testing using a human papillomavirus (HPV) genotyping assay which detects up to 28 types and includes a cellularity control. In addition to the HPV assay swabs will be tested using a 16S Ribosomal RNA PCR. Results will be experimental only and not influence the standard of care treatment provision.

Intervention Type
Other

Primary outcome(s)
The number of eligible individuals approached versus the number who consented measured using data collected in study records at the end of the recruitment period.

Key secondary outcome(s))

The following secondary outcome measures will be assessed at the end of the recruitment period:
1. The quality of self-taken and clinician-taken vaginal swabs to support HPV and microbial molecular testing measured using qualitative and quantitative assay (laboratory) outputs for microbial and housekeeping targets (PCR yes/no and Ct values)
2. Feasibility to collate information on vaginal hygiene procedures and acceptability of vaginal sampling in transgender and non-binary people with neovaginas (TGNBP) measured using the level of completion of the questionnaire
3. The proportion of TGNBP willing in principle to engage in a longitudinal study to assess the microbial environment of neovaginas (i.e. involving the collection of sequential samples) measured using the response in the questionnaire to the theoretical willingness to take part in a longer-term study

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Transgender or non-binary person who has had a vaginal construction procedure
2. Ability to provide informed consent
3. Aged 18 years and older (no upper age limit)

Participant type(s)
Service user

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
Female

Total final enrolment
16

Key exclusion criteria
1. Inability to provide informed consent
2. Vaginal construction in the last 3 months
3. Participation in other interventional research project in the last 30 days

Date of first enrolment
03/06/2024

Date of final enrolment
03/06/2025

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Chalmers Sexual Health Centre
2a Chalmers Street
Edinburgh
Lothian
Scotland
EH3 9ES

Sponsor information

Organisation
University of Edinburgh

ROR
https://ror.org/01nrxwf90

Organisation
NHS Lothian

ROR
https://ror.org/03q82t418

Funder(s)

Funder type
University/education

Funder Name
University of Glasgow

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Chief Scientist Office

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Kate Cuschieri, Kate.Cuschieri@nhslothian.scot.nhs.uk. No data containing any personally identifiable information will be made available to external researchers. Anonymised lab data will be made available as will aggregate data from the questionnaire.

IPD sharing plan summary
Available on request

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