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Urinary tract infection diagnosis in pregnancy by volatile organic compound analysis

Submission date
31/03/2021

Recruitment status
No longer recruiting

Registration date
22/04/2021

Overall study status
Completed

Last Edited
04/05/2021

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Urinary tract infections (UTIs) are common in pregnancy, affecting up to one in ten women. Some of these women have symptoms to warn them but others do not. UTIs can lead to complications in pregnancy which can affect both the mother and the baby and therefore diagnosis in a timely fashion is important. The current rapid tests used in clinics are not very accurate to diagnose UTIs. Consequently, it is currently recommended that all women provide a urine sample when they book their pregnancy with their community midwife which is sent to the laboratory to be cultured. If bacteria grow additional tests are done to determine which antibiotics will be effective at treating that bacteria. This process can be repeated several times throughout pregnancy. This is a time consuming and expensive process which can lead to delays in starting treatment. A new technology that mimics the human nose has been recently shown to accurately diagnose several human diseases including various infections. The aim of this study is to find out whether this technology, which could be available as a bedside test, can diagnose UTIs in pregnancy.

Who can participate?
Pregnant women aged 18 and over presenting to the hospital for clinical care

What does the study involve?
Participants will be asked to give a sample of urine from the middle of the stream (midstream urine sample) for routine laboratory analysis (this is part of routine antenatal care). Urine left over after this analysis will be used for this study. The researchers will also use information from participants' medical records. They will only use information that they need for this study.

What are the possible benefits and risks of participating?
There is no direct benefit to the patient taking part but knowledge gained will help patients in the future. The study could lead to commercial gain for the University of Warwick and/or collaborators. There are no known risks to taking part in this study.

Where is the study run from?
University Hospitals Coventry & Warwickshire NHS Trust (UK)

When is the study starting and how long is it expected to run for?
November 2019 to December 2023

Who is funding the study?
The Warwick-Wellcome Translational Partnership (UK)

Who is the main contact?
Dr Lauren Lacey
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Contact information

Type(s)
Scientific

Contact name
Dr Lauren Lacey

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Version 0.9

Study information

Scientific Title
Point of care diagnosis of urinary tract infections in pregnancy by volatile organic compound analysis

Study objectives
To optimise volatile organic compound (VOC) detection technology for urinary tract infections (UTIs) and then be able to screen for and diagnose culture-positive UTIs in pregnancy including asymptomatic bacteriuria, symptomatic cystitis and pyelonephritis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/03/2021, North West - Greater Manchester South Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, M1 3DZ, UK; +44 (0)207 104 8221, +44 (0)207 104 8063; gmsouth.rec@hra.nhs.uk), REC ref: 20/NW/0450

Study design
Prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Urinary tract infections in pregnancy

Interventions
Volatile organic compound analysis of a midstream urine sample, compared to microscopy culture and sensitivity testing of midstream urine sample and chemical dipstick test results.

The researchers will use a volatile organic compound (VOC) analysis (gas chromatography - ion mobility spectrometer [GC-IMS]) machine to identify specific VOC patterns/chemical associated with UTIs from urine samples of pregnant women. These women will be followed up until they have the results of the comparator test (the midstream urine microscopy, culture and sensitivity test). This takes approximately 5-7 days from when the sample is sent to the laboratory.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

VOC detection technology, either GC-IMS or the Electronic Nose

Primary outcome measure
The diagnostic accuracy of VOC analysis of midstream urine sample compared to the “Gold Standard” of microscopy, culture and sensitivity testing and compared to the chemical dipstick test, measured at a single timepoint

Secondary outcome measures
The causative organism of the urinary tract infection detected by VOC analysis at a single timepoint

Overall study start date
01/11/2019

Completion date
31/12/2023

Eligibility

Key inclusion criteria
Pregnant women, either confirmed by urinary pregnancy test in the first trimester or with other clinical signs of pregnancy

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
360

Key exclusion criteria
Women who are not able to give informed consent

Date of first enrolment
12/04/2021

Date of final enrolment
31/07/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals Coventry & Warwickshire NHS Trust
Clifford Bridge Road
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Sponsor information

Organisation
University of Warwick

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Sponsor type
University/education

Website
http://www2.warwick.ac.uk/

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Research organisation

Funder Name
Warwick-Wellcome Translational Partnership

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal in Obstetrics & Gynaecology field

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Lauren Lacey (l.lacey.1@warwick.ac.uk). Any data provided will be anonymised and discussed with the University of Warwick sponsorship team.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1.0	01/04/2021	04/05/2021	No	Yes
Protocol file	version V1.0	01/04/2021	04/05/2021	No	No
HRA research summary			28/06/2023	No	No