

# Urinary tract infection diagnosis in pregnancy by volatile organic compound analysis

<b>Submission date</b> 31/03/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 22/04/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/05/2021	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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  
l.lacey.1@warwick.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Lauren Lacey

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
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

### **Study type(s)**

Diagnostic

### **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(s)**

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

### **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**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**

United Kingdom

England

**Study participating centre**

University Hospitals Coventry & Warwickshire NHS Trust

Clifford Bridge Road

Coventry

United Kingdom

CV2 2DX

## Sponsor information

## Organisation

University of Warwick

## ROR

<https://ror.org/01a77tt86>

## Funder(s)

### Funder type

Research organisation

### Funder Name

Warwick-Wellcome Translational Partnership

## Results and Publications

### 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](mailto: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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	version V1.0	01/04/2021	04/05/2021	No	Yes
<a href="#">Protocol file</a>	version V1.0	01/04/2021	04/05/2021	No	No