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# Point-of-care testing for gastrointestinal pathogens

**Submission date**
20/02/2017

**Recruitment status**
No longer recruiting

**Registration date**
21/02/2017

**Overall study status**
Completed

**Last Edited**
10/05/2023

**Condition category**
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Many adults patient are admitted to hospital with diarrhoea every year. Some of these patients have infections and some have diarrhoea for other reasons. Patients with infections need to be isolated in a side room quickly to stop their infection from spreading to other patients. Some patients with infection will also need specific antibiotic treatment whilst others will not. The current tests that the NHS uses to look for infection in patients with diarrhoea take up to 5 days for a result. This means whilst the test result is awaited all patients with diarrhoea are put in a side room in case they have an infection and doctors have to make an educated guess as to who to treat with antibiotics. There are new tests available that are as accurate as standard laboratory tests and can generate a result in one hour. These are called molecular, point-of-care tests (POCT). The testing device is small and easy to use and so can be used at the patient's bedside rather than in a laboratory. This means that when a patient comes in with diarrhoea the doctors can know very quickly if they need to be isolated and if they need antibiotics or not. As the test is new there is no information as to whether testing patients like this will improve their care or be cost effective for the NHS. The aim of this study is to find out whether using this new test at patient's bedsides improves the way they are cared for and the way that side rooms are used in hospital.

Who can participate?
Adult patients in a Southampton General Hospital who have had sudden diarrhoea or vomiting.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group have their stools tested immediately using the molecular, point-of-care test (POCT) device. The results are then passed onto the healthcare team so that they can start antibiotic treatment if they need it. A further stool sample is also taken to be stored and tested at a later date. Those in the second group are managed according to standard practices, which involve having stool samples sent to the laboratory for testing. Throughout their hospital stay, patients in both groups have their medical records reviewed in order to find out how long they are kept in isolation in a side room and what care they receive, as well as completing an optional survey about their satisfaction with the care received.

What are the possible benefits and risks of participating?
It is not known whether having the new test will lead to improvements in patient care but it is possible that patients will directly benefit in terms of being cared for in the correct environment and having the antibiotic treatment given or withheld as appropriate. There are no anticipated risks involved with participating.

Where is the study run from?
Southampton General Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2016 to March 2020

Who is funding the study?
Biofire Diagnostics, LLC (UK)

Who is the main contact?
Ms Emma Levell
emma.levell@uhs.nhs.uk

# Contact information

### Type(s)
Scientific

### Contact name
Dr Tristan Clark

### Contact details
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# Additional identifiers

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

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
33068

# Study information

## Scientific Title
Randomised controlled trial comparing syndromic molecular point-of-care testing for gastrointestinal pathogens with standard clinical care, in adults presenting to secondary care with suspected infectious gastroenteritis (GastroPOC Trial)

## Acronym
GastroPOC

## Study objectives
The aim of this study is to examine the clinical impact of a rapid, molecular, point-of-care test (POCT) for gastrointestinal pathogens detection (FilmArray Gastrointestinal Panel, BioFire, Salt Lake City, Utah, USA, owned by bioMérieux; CE marked) in patients presenting with acute diarrhoea and/or vomiting, compared to routine clinical care.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
West Midlands - Solihull Research Ethics Committee, 09/01/2017, ref: 16/WM/0515

## Study design
Randomised; Interventional; Design type: Diagnosis, Process of Care, Device

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Gastroenteritis

## Interventions
Participants will be randomised to one of two groups in a 1:1 ratio using an internet-based randomisation service using random permuted blocks of varying sizes (4, 6 and 8).

Intervention group: Participants will have a molecular Point-of-Care test (POCT) performed on stool with the results immediately communicated to the clinical team, infection prevention and control (IPAC) team and the patient. Subsequent clinical management decisions are made independently by the responsible clinical and IPAC teams.

Control group: Participants will be managed according to routine clinical care, where testing for pathogens in stool is at the discretion of the responsible clinical team and where performed will use the standard NHS laboratory testing. A stool sample also will be taken and stored and tested at later date with the POCT to allow direct comparison of the pathogens detected between the groups (i.e. missed diagnoses).

For participants in both groups, clinical and demographic data is collected at enrolment and for outcome measures is collected retrospectively from case notes and electronic hospital information systems. Patient satisfaction surveys are performed immediately prior to discharge. There is no follow up.

## Intervention Type
Other

## Primary outcome(s)
Duration of time in side room isolation is measured by retrospective review of case notes and electronic hospital information systems for the duration of hospitalisation (up to 30 days maximum)

## Key secondary outcome(s))
1. Proportion of patients isolated in a side room is measured by retrospective review of case notes and electronic hospital information systems for the duration of hospitalisation (up to 30 days maximum)
2. Time to patient isolation in a side room is measured by retrospective review of case notes and electronic hospital information systems for the duration of hospitalisation (up to 30 days maximum)
3. Time to de-isolation in pathogen negative patients is measured by retrospective review of case notes and electronic hospital information systems for the duration of hospitalisation (up to 30 days maximum)
4. Proportion of patients treated with antibiotics is measured by retrospective review of case notes and electronic hospital information systems for the duration of hospitalisation (up to 30 days maximum)
5. Time to treatment with antibiotics is measured by retrospective review of case notes and electronic hospital information systems for the duration of hospitalisation (up to 30 days maximum)
6. Duration of antibiotics is measured by retrospective review of case notes and electronic hospital information systems for the duration of hospitalisation (up to 30 days maximum)
7. Duration of hospitalisation is measured by retrospective review of case notes and electronic hospital information systems for the duration of hospitalisation (up to 30 days maximum)
8. Proportion of patients with a pathogen detected is measured by retrospective review of case notes and electronic hospital information systems for the duration of hospitalisation (up to 30 days maximum)
9. Time to diagnosis is measured by retrospective review of case notes and electronic hospital information systems for the duration of hospitalisation (up to 30 days maximum)
10. Concordance between results obtained from rectal swab and stool culture is measured retrospectively at a time point >30 days post enrolment by comparing the result of diagnostic testing
11. Turnaround time is measured by retrospective review of case notes and electronic hospital information systems for the duration of hospitalisation (up to 30 days maximum)
12. Patient satisfaction is measured using a validating NHS survey tool at the point of discharge
13. Safety is measured by retrospective review of case notes and electronic hospital information systems for the duration of hospitalisation (up to 30 days maximum)

Added 21/03/2019:
14. Proportion of pathogen-positive patients de-isolated, measured by retrospective review of case notes and electronic hospital information systems for the duration of hospitalisation (up to

30 days maximum)
15. Proportion of pathogen-negative patients de-isolated, measured by retrospective review of case notes and electronic hospital information systems for the duration of hospitalisation (up to 30 days maximum)

Added 04/09/2020:
Measured by retrospective review of case notes and electronic hospital information systems for the duration of hospitalisation (up to 30 days where appropriate):
16. Duration of time in a side room for pathogen positive patients
17. Duration of time in a side room for pathogen negative patients
18. Proportion of pathogen positive patients isolated in a side room
19. Proportion of pathogen negative patients isolated in a side room
20. Proportion of patients with bacterial gastroenteritis treated with antibiotics
21. Proportion of patients without bacterial gastroenteritis treated with antibiotics
22. Other medication use, complications (inc Acute Kidney Injury), ICU admissions, 30-day mortality, representation and readmission

Added 28/05/2021:
Missed diagnoses measured by retrospective review of case notes and electronic hospital information systems for the duration of hospitalisation (up to 30 days maximum)

### Completion date
17/03/2020

# Eligibility

### Key inclusion criteria
1. Aged 18 years or over
2. Has the capacity to give informed, written consent and is able and willing to adhere to the study procedures
3. A patient in Southampton General Hospital ED, AMU, ASU or inpatient ward (if admitted directly to an inpatient ward)
4. Can be recruited to the study within a 48 hour period of first triage by ED staff OR within a 48 hour period of arrival on AMU or ASU or inpatient ward (if admitted directly to AMU/ASU to these areas)
5. Has an acute diarrhoeal illness and/or vomiting*
5. Has a duration of illness less of than or equal to 14 days

*An episode of acute diarrhoea is defined as the passage of at least 3 loose stools for at least 1 day.
(AMU = acute medical unit, ASU = acute surgical unit, ED = emergency department)

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Total final enrolment
278

### Key exclusion criteria
1. Patients not fulfilling inclusion criteria
2. A palliative approach being taken by the treating clinicians
3. Previously included in this study and re-presenting within the last 30 days after hospital discharge
4. Declines to give stool sample and/or rectal swab

Involvement in other research trials is not necessarily an exclusion criterion. Concurrent, prior or subsequent enrolment in an observational study is not expected to be an exclusion criterion, except at the discretion of the principal investigator.

### Date of first enrolment
01/03/2017

### Date of final enrolment
01/03/2020

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Southampton General Hospital**
Tremona Road
Southampton
United Kingdom
SO16 6YD

## Sponsor information

### Organisation
University Hospital Southampton NHS Foundation Trust

**ROR**
https://ror.org/0485axj58

# Funder(s)

**Funder type**
Industry

**Funder Name**
Biofire Diagnostics, LLC

# 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 Prof. Tristan Clark or Dr Nathan Brendish (t.w.clark@soton.ac.uk, n.brendish@soton.ac.uk); data are available upon reasonable request, participants' data are fully anonymised, and all participants have given written consent for future data use.

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 25/04/2023 | 02/05/2023 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | version V2.1 | 26/01/2017 | 21/02/2017 | No | Yes |
| Protocol (other) | | 16/06/2021 | 10/10/2022 | No | No |
| Protocol file | version 2.0 | 30/05/2018 | 10/10/2022 | No | No |