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Whole gut transit time measurement using MRI in constipation

Submission date 17/11/2025	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 11/12/2025	**Overall study status** Ongoing	
Last Edited 11/12/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Patients with constipation may have an impaired gastrointestinal transit time, i.e. the time it takes for food to travel through their intestines; having this information may help doctors to choose treatment. The current method to measure this gastrointestinal transit time uses X-rays, which use harmful radiation and do not provide good-quality images of the bowel.

Who can participate?
Patients aged 7 years and above who have been diagnosed with chronic constipation are eligible to participate in this study.

What does the study involve?
The research team have invented a new method to measure gastrointestinal transit time. The new method uses small TransiCap MRI visible capsules. They are easy to swallow but do not dissolve in the body and do not release any substance. The TransiCap capsules contain a liquid (of oil and water) that shows up brightly when imaged using Magnetic Resonance Imaging or MRI. MRI is a common and safe medical imaging technique to locate the TransiCap capsules inside the intestines of the patients and see how fast or slow they travelled.

Taking part in the study will involve attending 3 study visits. The first visit, called the baseline visit, will take place either at the hospital or remotely via a telephone/video call, at the discretion of the local hospital. The next two visits are for MRI scans and will take place at the local MRI unit. The study will involve the participant swallowing 20 mini-capsules a day on Day 1, Day 2 and Day 3 (60 capsules in total over the three days), followed by two MRI scans, one at Day 5 and one at Day 28. The capsules can be swallowed with liquids, smoothies or yoghurts to make swallowing easier. The study will also collect information through questionnaires.

What are the possible benefits and risks of participating?
We cannot guarantee any treatment benefits for the participants; however, their involvement in the study will help to make this new test available in the future for people with similar conditions.

There is a small risk of choking or aspirating (when food enters the airways or lungs) when anything is taken orally, like food. This risk is the same as swallowing the capsules. To minimise this risk, we will exclude participants if they have issues with swallowing. In the unlikely event that aspiration does happen, the TransiCap capsules are expected to stay intact and could be removed in hospital with a bronchoscope under anaesthetic. The capsules are made of a material that is medically safe and sterile, can be easily swallowed, will not burst or break down in the body, but pass out with the stools after a few days. The filling of the capsules is not expected to interact with the body; it only helps us to see the capsules as they travel along the intestines.

Where is the study run from?
This is a multicentre study and will be running simultaneously in Nottingham University Hospital, University College London Hospital and the Greater Ormond Street Hospital for children.

When is the study starting and how long is it expected to run for?
May 2026 to September 2027

Who is funding the study?
The National Institute for Health and Care Research (NIHR), i4i grant, UK.

Who is the main contact?
Dr. Luca Marciani, luca.marciani@nottingham.ac.uk

Contact information

Type(s)
Principal investigator

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Integrated Research Application System (IRAS)
342112

Protocol serial number
23GDI013

National Institute for Health and Care Research (NIHR)
207480

Central Portfolio Management System (CPMS)
61823

Study information

Scientific Title
A multicentre clinical investigation to assess safety and performance of TransiCap, swallowable MRI-visible capsules for monitoring gut transit time in constipation

Acronym
MAGIC3

Study objectives
The primary objective of this study is to test the performance of the TransiCap device as a method for obtaining whole gut transit time in patients 7 years of age and above with chronic constipation, and to assess the safety of the TransiCap device in doing so.

Ethics approval required
Ethics approval required

Ethics approval(s)
notYetSubmitted

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Device feasibility

Study type(s)
Diagnostic, Safety

Health condition(s) or problem(s) studied
Performance of the TransiCap device as a method for obtaining whole gut transit time in Patients (Age-7 years old and above) with Chronic Constipation.

Interventions
This study is a Pre-market, Pivotal confirmatory clinical investigation of a medical device. Single arm, unblinded, multi-centre, case series.

The research team have invented a new method to measure gastrointestinal transit time. The new method uses TransiCap MRI visible capsules, which are very small. They are easy to swallow but do not dissolve in the body and do not release any substance. Taking part in the study will involve attending 3 study visits. The first visit, called the baseline visit, will take place either at the hospital or remotely via a telephone/video call, at the discretion of the local hospital. The next two visits are for MRI scans and will take place at the local MRI unit. The study will involve the participant swallowing 20 mini-capsules a day on Day 1, Day 2 and Day 3 (60 capsules in total over the three days), followed by two MRI scans, one at Day 5 and one at Day 28. The capsules can be swallowed with liquids, smoothies or yoghurts to make swallowing easier. The study will also collect information on bowel habits, symptoms and quality of life through questionnaires during the study.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
TransiCap

Primary outcome(s)
1. Whole gut transit time measured using TransiCap MRI visible capsules and MRI scanning at baseline, days 5 and 28

Key secondary outcome(s))
1. Number of Serious Adverse Events measured using data collected from electronic Case Report Forms (eCRF) at days 5 and 28

2. Patient acceptability of swallowing the TransiCap MRI visible capsules (usability and acceptability performance) measured using questionnaires at days 1, 2 and 3

3. Non-inferiority, sensitivity and specificity of the TransiCap test in measuring WGTT and in diagnosing slow transit constipation as compared to reference standard (recorded in the clinical notes and performed within 6 months of this study) measured using analysed MRI images at day 5

4. Identification of any undesirable side effects (Adverse Device Effects) measured using data collected from eCRF at Days 5 and 28

5. Number of TransiCap MRI visible capsules swallowed measured using MRI images at days 1, 2 and 3

6. Visibility of capsules measured using MRI scans at day 5

7. Number of people completing the MRI study measured using data collected from the eCRF at day 28

8. Number of patients withdrawn and reason for withdrawal measured using data collected from the eCRF at at time of withdrawal

9. Health-related quality of life measured using the EQ-5D-Y (for children and adolescents) or EQ-5D-5L (adults) at visit 1 and day 6

10. Self-rated overall health measured using the EuroQol Visual Analogue Scale (EQ VAS) score, AC-QoL score (parents/carers quality of life) at visit 1, days 0, 1, 2, 3, 4, 5 and 6

11. Constipation measured using the Patient Assessment of ConstipationSymptoms (PAC-SYM) questionnaire at day 0

12. Patient symptoms (flatulence, bloating and abdominal pain) measured using a questionnaire at days 0, 1, 2, 3, 4, 5 and 6

13. Stool form measured using the Bristol stool form chart at days 0, 1, 2, 3, 4, 5 and 6

14. Demographics including age, sex, height, weight, ethnicity, socioeconomic status measured using data collected in study records at at visit 1

15. Health economic outcome measured using Clinical Service Receipt Inventory data at day 0

Completion date
30/11/2027

Eligibility

Key inclusion criteria
1. Male or female patients aged 7 years old and above
2. Having a clinical diagnosis of CC, defined broadly as characterised by stools that are infrequent and/or difficult to pass in the absence of mucosal/structural abnormalities.
3. Having had a transit study (either X-ray or gamma scintigraphy) organised within 6 months of the TransiCap test and carried out according to the local site standard procedures
4. Willing to consent for participation in the clinical investigation or, if below 16 years of age,

willing to give assent for participation in the clinical investigation and have a parent/carer willing to give informed consent for participation in the clinical investigation.
5. Able (in the Investigators opinion) and willing to comply with all clinical investigation requirements.
6. Willing to allow his or her General Practitioner and consultant, if appropriate, to be notified of participation in the clinical investigation.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
7 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Female participants who are pregnant, lactating or planning pregnancy during the course of the clinical investigation. This will be self-reported.
2. Any history of gastrointestinal surgery that could affect gastrointestinal function, such as cholecystectomy, colectomy or small bowel resection.
3. Existing antegrade colonic enema (ACE) procedure.
4. Contraindications for MRI scanning i.e. metallic implants, pacemakers, history of metallic foreign body in eye(s) and penetrating eye injury.
5. Inability to lie flat and relatively still for less than 5 minutes.
6. Poor ability to understand instructions or the consent process
7. Difficulties in swallowing tablets, dysphagia or a diagnosis of oesophageal dysmotility
8. The following disease or disorder: an active eating disorder (e.g. anorexia), known presence of bowel strictures, inflammatory bowel diseases, Hirschsprung disease, congenital anorectal malformations, Chronic Intestinal pseudo-obstruction.
9. Unable or unwilling to temporarily discontinue for the duration of the study drugs influencing gut function such as: laxatives, anticholinergics, prokinetics, opioid analgesics (tramadol, morphine, fentanyl, oxycodone, co-codamol and codydramol); antispasmodic Buscopan (hyoscine butylbromide, also known as scopolamine butylbromide
10. Participation in another research clinical investigation involving an investigational product in the past 12 weeks

Date of first enrolment
01/05/2026

Date of final enrolment
30/09/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
Derby Road
Nottingham
England
NG7 2UH

Study participating centre
Great Ormond Street Hospital for Children
Great Ormond Street
London
England
WC1N 3JH

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
England
NW1 2PG

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Not defined

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository, in keeping with the funder NIHR position on the sharing of research data. (Repository address to be confirmed)

IPD sharing plan summary
Stored in publicly available repository