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The high-resolution three-dimensional magnetic detector system 3D-MAGMA accurately measures gastric and small bowel motility in people with type 2 diabetes with neuropathy

Submission date
10/08/2017

Recruitment status
No longer recruiting

Registration date
15/08/2017

Overall study status
Completed

Last Edited
01/07/2020

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Gastroparesis is a motility disorder where the stomach can't empty itself in the normal way and food passes through the stomach more slowly than usual. It is an important complication of diabetes. Motility disorders are underdiagnosed and can lead to unexplained hypoglycemia (low blood sugar). Currently, diagnostic options are limited, and all established methods have disadvantages. The 3D-MAGMA system is capable of reliably measuring stomach and small intestine motility. The aim of this study is to find out whether 3D-MAGMA is able to detect changes in intestinal motility in people with type 2 diabetes and healthy volunteers.

Who can participate?
Patients with type 2 diabetes and healthy volunteers, aged 18-85

What does the study involve?
The participants are positioned in a chair with the 3D-MAGMA-unit attached to it. A magnet is orally administered with 70 ml of water after the recording is started. The time taken for the magnet to pass through the stomach and small intestine is recorded. If the marker stays in the stomach, the measurement is stopped after a minimum of three hours.

What are the possible benefits and risks of participating?
A possible benefit to the participants would be the detection of a gastroparesis which requires medical treatment. 3D-MAGMA is a low risk measuring system. The magnet itself is coated by an inert synthetic material and does not interact with its surroundings. As the marker is magnetic it has to be excreted before having an MRI examination.

Where is the study run from?
Friedrich-Schiller-Universität (Germany)

When is the study starting and how long is it expected to run for?
May 2011 to January 2019

Who is funding the study?
University Hospital Jena (Germany)

Who is the main contact?
Mr Veit Yves Pascal Jacob

Contact information

Type(s)
Scientific

Contact name
Mr Veit Yves Pascal Jacob

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1.1

Study information

Scientific Title
Measuring people with type 2 diabetes using the high-resolution three-dimensional magnetic detector system 3D-MAGMA - compared to young healthy volunteers to detect changes in gastic and small bowl motility

Study objectives
The aim of the current trial is to determine if 3D-MAGMA is able to detect changes in gastric and small bowel motility in patients with type 2 diabetes compared to healthy controls.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local ethics board of Friedrich-Schiller-University Jena, 12/08/2011, ref: 3179- 07/11

Study design
Single-centre two-arm open trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
People with type 2 diabetes using insulin and peripheral neuropathy

Interventions
The intervention was an incorporated magnetic capsule detected with the high-resolution three-dimensional magnetic detector system 3D-MAGMA. This system is able to track the position and movement of the marker with high accuracy.

Each person was measured once. The measurement took place in the former outpatients department of the KIM III (Department of Internal Medicine III, Endocrinology and Metabolic Diseases University Hospital Jena). The procedure was started between 8:00am and 9:30 am, after fasting for a minimum of 8 hours. Height, weight, blood glucose level, HbA1c, blood pressure and heart rate were all measured prior to the procedure by a study nurse, and a relevant symptomatic history was obtained with a standardized interview (nausea, vomiting, sustained bloating and abdominal and epigastric pain). The whole procedure was supervised by a postgraduate student.

More detailed information regarding the 3D-MAGMA is available at: https://www.ncbi.nlm.nih.gov/pubmed/19095766

Intervention Type
Device

Primary outcome measure
Residence time (min) of the capsule in the stomach measured by 3D-MAGMA

Secondary outcome measures
1. Residence time (min) of the capsule in the duodenum measured by 3D-MAGMA
2. Residence time (min) of the capsule in the first 50 cm of the jejunum measured by 3D-MAGMA

Overall study start date
12/05/2011

Completion date
01/01/2019

Eligibility

Key inclusion criteria
1. Age 18-85 years
2. NSS >4/10 and NDS >6/10
3. Blood glucose 4-12 mmol/l before testing
4. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
20

Total final enrolment
37

Key exclusion criteria
1. Surgery of stomach or small bowel
2. Opioids, erythromycin, prokinetic agents, L-dopa, ß-agonists, benzodiazepines, ondansetron, tricyclic antidepressives, atropine
3. Eating disorder, portal hypertension, gastric cancer, systemic sclerosis, myotonic dystrophy
4. Pregnancy
5. Implanted cardiac pacemaker/defibrillator

Date of first enrolment
12/03/2013

Date of final enrolment
02/07/2014

Locations

Countries of recruitment
Germany

Study participating centre
Friedrich-Schiller-Universität
Department of Internal Medicine IV
(Gastroenterology, Hepatology and Infectious Diseases)
Am Klinikum 1
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07747

Sponsor information

Organisation
University Hospital Jena

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.kim4.uniklinikum-jena.de

ROR
https://ror.org/035rzkx15

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universitätsklinikum Jena

Alternative Name(s)
Jena University Hospital, UKJ

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Germany

Results and Publications

Publication and dissemination plan
Additional documents such as study protocol and statistical analysis plan are available upon request. Planned publication in a high-impact peer reviewed journal within the next 12 months.

Intention to publish date
15/02/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mr Veit Yves Pascal Jacob.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2020	01/07/2020	Yes	No