

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

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Registration date 15/08/2017	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/07/2020	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number
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 gastric and small bowel 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

Primary study design

Interventional

Study design

Single-centre two-arm open trial

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

85 Years

Sex

All

Total final enrolment

37

Key exclusion criteria

1. Surgery of stomach or small bowel
2. Opioids, erythromycin, prokinetic agents, L-dopa, β -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
Jena
Germany
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Sponsor information

Organisation

University Hospital Jena

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

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