# 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	Recruitment status  No longer recruiting	Prospectively registered		
10/08/2017		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
15/08/2017	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
01/07/2020	Nutritional, Metabolic, Endocrine			

#### 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

#### **ORCID ID**

https://orcid.org/0000-0001-9216-3226

#### Contact details

Klinik für Innere Medizin IV Gastroenterologie, Hepatologie und Infektiologie Universitätsklinikum Jena, Friedrich Schiller Universität Jena Am Klinikum 1 Jena Germany 07747

# Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

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 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

#### 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, 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 Jena Germany 07747

# 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes