Effect of apple cider vinegar on delayed gastric emptying in people with type 1 diabetes mellitus

	Submission date 23/08/2007	Recruitment status No longer recruiting	Prospectively registered		
			[_] Protocol		
	Registration date 23/08/2007	Overall study status Completed	[] Statistical analysis plan		
			[X] Results		
	Last Edited	Condition category	Individual participant data		
	31/12/2020	Nutritional, Metabolic, Endocrine			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

Contact name Dr Joanna Hlebowicz

Contact details

Department of Medicine Malmo University Hospital Ingang 35 Malmo Sweden 205 02 +46 (0)40 331000 Joanna.Hlebowicz@skane.se

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR1004

Study information

Scientific Title Effect of apple cider vinegar on delayed gastric emptying in people with type 1 diabetes mellitus

Study objectives

The aim was to study the effect of apple cider vinegar on the rate of gastric emptying on insulindependent diabetes mellitus patients with diabetic gastroparesis.

Ethics approval required Old ethics approval format

Ethics approval(s) Not provided at time of registration

Study design Non-randomised cross over study. Patients are their own controls.

Primary study design Interventional

Secondary study design Non randomised controlled trial

Study setting(s) Not specified

Study type(s) Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Gastroparesis, diabetes mellitus type 1 (DM type I)

Interventions

Gastric emptying rate (GER) was measured by standardised real time ultrasonography on the condition that fasting blood glucose was 3.5 to 9.0 mmol/l. Gastric emptying rate was calculated as the percentage change in the antral cross-sectional area 15 and 90 minutes after ingestion of 300 g rice pudding and two decilitres of water or 300 g rice pudding and two decilitres of water and 30 millilitres of apple cider vinegar. The subjects drank 200 ml water daily before breakfast one week before the measurement of GER. The same subjects drank 200 ml with 30 ml vinegar daily before breakfast for two weeks before the measurement of GER.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s) Apple cider vinegar

Primary outcome measure The effect of vinegar on the rate of gastric emptying was statistically significant (p <0.05).

Secondary outcome measures No secondary outcome measures

Overall study start date 01/09/2002

Completion date 01/09/2005

Eligibility

Key inclusion criteria Type 1 diabetes patients with diagnosed gastroparesis

Participant type(s) Patient

Age group Not Specified

Sex Not Specified

Target number of participants 10

Total final enrolment 10

Key exclusion criteria 1. Renal failure 2. Prior gastric outlet obstruction

3. Connective tissue diseases

Date of first enrolment 01/09/2002

Date of final enrolment 01/09/2005

Locations

Countries of recruitment Netherlands

Sweden

Study participating centre Department of Medicine Malmo Sweden 205 02

Sponsor information

Organisation Malmo University Hospital (Sweden)

Sponsor details Department of Medicine Ingang 35 Malmo Sweden 205 02

Sponsor type Hospital/treatment centre

Website http://www.hand.mas.lu.se/malmo_unv_hosp.htm

ROR https://ror.org/02z31g829

Funder(s)

Funder type Research organisation

Funder Name Malmo Diabetes Association (Sweden)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	20/12/2007	31/12/2020	Yes	No