ISRCTN13565602 https://doi.org/10.1186/ISRCTN13565602

Investigation into the use of radiofrequency ablation for the treatment of watermelon stomach

Submission date	Recruitment status	[_] Prospectively registered
06/06/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/06/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/09/2020	Circulatory System	

Plain English summary of protocol

Background and study aims
Gastric antral vascular ectasia (GAVE), also known as watermelon stomach, is a rare condition in which the lining of the stomach bleeds, giving it the characteristic stripes of a watermelon. The exact cause is unknown, however it is associated with the dilation (widening) of the small blood vessels in the last part of the stomach (antrum), which lead to bleeding. This often causes severe anaemia (low red blood cell count or iron levels), which requires treatment with iron supplements or blood transfusions. Radiofrequency ablation (RFA) is a procedure in which the affected tissue (in this case, the dilated blood vessels) are destroyed using heat. The procedure is guided by an endoscope (camera on the end of a thin, flexible tube that is passed into the stomach via the mouth), and targets the affected blood vessels at the bottom of the stomach. The aim of this study is to test the effectiveness of the endoscopic RFA procedure in the treatment of GAVE.

Who can participate?
Adult patients with GAVE that has led to anaemia, who are undergoing endoscopic RFA treatment.

What does the study involve?
All participants undergo RFA treatment for their GAVE. Immediately before the treatment and six months later, participants complete a questionnaire about their quality of life. 6-8 weeks after the RFA treatment, part of standard care given involves a follow up endoscopy to assess how well the treatment has worked. The results of this are recorded by the investigators. Over the 6 months after treatment, the participant's medical notes are reviewed in order to record the amount of blood transfusions they have had as well as their red blood cell count (sign of anaemia).

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
University College Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2015 to March 2018

Who is funding the study?
University College London (UK)

Who is the main contact?
Dr Rehan Haidry

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1

Study information

Scientific Title
RadioFrequency Ablation for Gastric Antral Vascular Ectasia

Acronym
RFA for GAVE

Study objectives

The aim of this study is to investigate the effectiveness of radiofrequency ablation (RFA) for the treatment of gastric antral vascular ectasia (GAVE).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Central, 03/02/2016, ref: 16/LO/0149

Study design
Longitudinal case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Gastric antral vascular ectasia (GAVE)

Interventions
All patients receive radiofrequency ablation (RFA) for the treatment of gastric antral vascular ectasia (GAVE) coupled with standard care. The usual care pathway involves regular blood tests to assess the requirement for blood transfusions or iron supplementation both before and after any endoscopic intervention. Following a treatment with RFA, a repeat endoscopy is performed 6-8 weeks later to assess a response to treatment and apply further therapy should it be indicated. Should it be necessary to repeat RFA then a further endoscopy 6-8 weeks later may also be performed.

In this study, immediately before and six months after undergoing RFA, participants complete a quality of life questionnaire. In addition, over the six months following treatment, transfusion requirements and haemoglobin concentrations of patients and data from any follow up endoscopies is collected through medical note review in order to assess the effectiveness of the treatment pathway.

Intervention Type
Procedure/Surgery

Primary outcome measure

1. Quality of life is measured using the Functional Assessment of Chronic Illness Therapy - fatigue scale (FACIT-F) questionnaire at baseline (pre-RFA) and 6 months post-RFA
2. Number of red blood cell (RBC) packs transfused (transfusion requirement), parenteral iron requirements and haemoglobin concentrations (g/dL) are measured by reviewing patient notes and blood tests at baseline (pre-RFA) and 6 months post-RFA

Secondary outcome measures
1. Number of endoscopy treatment sessions are measured by reviewing patient notes at baseline (pre-RFA) and 6 months post-RFA
2. Percentage surface regression in macroscopically evident GAVE is measured during endoscopy at any follow up endoscopy in the 6 months post-treatment

Overall study start date
01/09/2015

Completion date
01/03/2018

Eligibility

Key inclusion criteria
1. Existing diagnosis of GAVE that has resulted in anaemia requiring either intravenous iron replacement or blood transfusion
2. Undergoing endoscopic treatment with RFA
3. Aged 18 years and over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Total final enrolment
20

Key exclusion criteria
1. Active malignancy
2. Anaemia due to other cause such as coeliac disease, small bowel pathology or haematological disease
3. Pregnancy

Date of first enrolment
01/09/2015

Date of final enrolment
01/09/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College Hospital
235 Euston Road
Fitzrovia, London
London
United Kingdom
NW1 2BU

Sponsor information

Organisation
University College London

Sponsor details
Joint Research Office
Gower Street
London
England
United Kingdom
WC1E 6BT

Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type

University/education

Funder Name
University College London

Alternative Name(s)
University College London in United Kingdom, Collegium Universitatis Londinensis, UCL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a Gastroenterology peer reviewed related journal.

Intention to publish date
01/09/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2019	07/09/2020	Yes	No
HRA research summary			28/06/2023	No	No