

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

<b>Submission date</b> 06/06/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 14/06/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/09/2020	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## 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**  
Dr Rehan Haidry

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**Contact details**  
University College Hospital  
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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?
<a href="#">Results article</a>	results	01/03/2019	07/09/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No