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Safety and efficacy of using NaviAid™ BGE device for endoscopic diagnosis and treatment

Submission date 08/11/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 14/11/2006	**Overall study status** Completed	
Last Edited 08/03/2019	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00398203

Protocol serial number
Protocol No. 1

Study information

Scientific Title
Safety and efficacy of using NaviAid™ BGE device for endoscopic diagnosis and treatment

Study objectives
Balloon Guided Endoscopy (BGE) is a procedure intended for the examination of the small intestine, which utilises the NaviAid™ BGE device in conjunction with a standard endoscope.

Hypothesis:
To assess the efficacy of the Naviaid™ Balloon Guided Endoscope (BGE) device, while used in conjunction with a standard endoscope for the diagnosis and treatment of the small intestine.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Open label randomised-controlled double arm single centre study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Small intestine abnormality

Interventions
The intervations in this study are enteroscopy and BGE procedure.

Intervention Type
Device

Phase
Not Specified

Primary outcome(s)
Depth of small intestine visualisation

Key secondary outcome(s))
The safety endpoint is incidence of treatment related major complications. Major complications are:
1. Blood transfusion
2. Adverse event requiring treatment associated with elongation of hospital stay for more than 24 hours beyond the standard at the specific site
3. Complications associated with permanent sequelae
4. Death

Completion date
31/07/2011

Eligibility

Key inclusion criteria
1. Male/female aged between 18 and 80 years (inclusive)
2. Subject is scheduled for endoscopic procedure after the case was reviewed by one of the investigators
3. Symptomatic subject defined as having at least one of the following signs or symptoms:
3.1. Abdominal pain
3.2. Cramps
3.3. Bloating
3.4. Diarrhoea
3.5. Nausea
3.6. Vomiting
3.7. Unexplained anaemia
3.8. Gastro-Intestinal (GI) bleeding from an unknown source
3.9. Small bowel abnormality on any imaging study
4. Subject able to comprehend and give informed consent for participation in this study
5. Signed informed consent form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Key exclusion criteria
1. Pregnancy
2. Acute bowel obstruction
3. Concomitant coumadin or warfarin use
4. Severe diverticulitis
5. Recent (within the last three months) coronary ischemia or Coronary Vascular Accident (CVA - stroke)
6. Any chronic unstable disease
7. Bleeding disorders
8. Needing emergency surgery
9. Any patient condition deemed too risky for BGE by the investigator

10. Known cognitive or psychiatric disorder
11. Physician objection
12. Concurrent participation in any other clinical trial

Date of first enrolment
01/01/2007

Date of final enrolment
31/07/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College Hospital
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
Smart Medical Systems Ltd (Israel)

ROR
https://ror.org/01w50vm31

Funder(s)

Funder type
Industry

Funder Name
Smart Medical Systems Ltd (Israel)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration