

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

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

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

Primary study design

Interventional

Study design

Open label randomised-controlled double arm single centre study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Small intestine abnormality

Interventions

The interventions 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