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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Ingvar Bjarnason

Contact details

King's College Hospital Denmark Hill London United Kingdom SE5 9RS

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number NCT00398203

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

Depth of small intestine visualisation

Secondary outcome measures

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

Overall study start date

01/01/2007

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

80 Years

Sex

Both

Target number of participants

60

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

England

United Kingdom

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

Sponsor information

Organisation

Smart Medical Systems Ltd (Israel)

Sponsor details

10 Hayetsira Street Ra'anana Israel 43663

Sponsor type

Industry

ROR

https://ror.org/01w50vm31

Funder(s)

Funder type

Industry

Funder Name

Smart Medical Systems Ltd (Israel)

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