The cost effectiveness of tube feeding versus oral nutritional supplements in hospitalized patients with IBD

Published: 10-04-2009
Last updated: 06-05-2024

The aim of the study is to assess the cost-effectiveness of implementation of tube feeding in hospitalized IBD patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON33890

Source
ToetsingOnline

Brief title
Tube feeding study

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Bowel Disease, Inflammatory Bowel Disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cost effectiveness, Hospital stay, IBD, Tube feeding

Outcome measures

Primary outcome

The reduction of hospital stay in days of 30%

Secondary outcome

Quality of life and psychopathology by psychological assessment using the IBDQ

questionnaire

Study description

Background summary

It is known that nutritional support is an important factor in the treatment of patients with inflammatory bowel disease (IBD) who experience an exacerbation leading to admittance to the hospital. We hypothesize that using tube feeding instead of using oral nutritional supplements can shorten the hospital stay in this group of patients. This will be studied in a randomized trial.

Study objective

The aim of the study is to assess the cost-effectiveness of implementation of tube feeding in hospitalized IBD patients.

Study design

Multicenter, randomized study will be performed with two treatment arms.

Intervention

Feeding
Group A will receive standard treatment with liquid oral nutritional supplements (nutri-drink, 4 times 200ml - 4 times 300kcal - per day). Group B will recieve standard therapy combined with tube feeding via a nasogastric tube (nutrison standard, 1500-2000ml per day; 100ml = 100kcal).

Study burden and risks

The nasogastric tube can be experienced as uncomfortable. Aspiration prneumonia is an infrequent complication of tube placement.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040
3000 CA ROTTERDAM
Nederland
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040
3000 CA ROTTERDAM
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

· Endoscopically or histologically proven Crohn*s disease or ulcerative colitis before 3 months prior to randomization
· Age 18-70 years
· Written informed consent
· Adequate contraception for males and females during treatment and

follow up (written confirmation)
· All therapy is permitted concomitant therapy
· Patients must be hospitalized

Exclusion criteria

· Pregnancy, breast-feeding
· Any other condition which in the opinion of the investigator would make the patient unsuitable for enrollment, or could interfere with the patient participating in and completing the study
· Total parental nutrition
· Bowel perforation
· Short bowel
· Neoplastic condition of the subject

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-07-2009
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	10-04-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL24552.078.08