# The effect of an extended use of enteral tube feeding sets on growth of microorganisms

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Gastrointestinal infections |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON57181

**Source**
ToetsingOnline

**Brief title**
EXTENSION

### Condition

- Gastrointestinal infections
- Bacterial infectious disorders

**Synonym**
gastroenteritis

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Medisch Spectrum Twente
**Source(s) of monetary or material Support:** Medisch Spectrum Twente

## Intervention

**Keyword:** enteral nutrition, medical waste, pathogen transmission, tube feeding

## Outcome measures

### Primary outcome

The amount of enteral tube feeding sets contaminated with microorganisms

### Secondary outcome

The number of contaminated tube feeding sets related to patient cultures

(retrieved from regular patient care) contaminated with the same

microorganism(s).

The number of patients with gastrointestinal events (i.e. diarrhea, vomiting,

nausea, abdominal pain) and new onset of sepsis;

The influence of SDD on the number of gastro-intestinal events and the growth

of microorganisms in enteral tube feeding sets;

The percentage of enteral tube feeding sets that did not endure 96 hours of

use, according to the durability checklist (appendix II);

Number of (serious) adverse events ((S)AE's).

# Study description

### Background summary

The increasing need for sustainability and reducing nursing workload has raised the question whether the current maximum 24-hour operating time of enteral tube feeding sets can safely be extended. Therefore, we have previously conducted a pilot study. This pilot study demonstrated that extended use (1 week) of enteral tube feeding sets may be feasible and safe. To confirm our preliminary results, we aim to investigate whether extended usage of enteral tube feeding sets is also safe when used in daily clinical practice.

### Study objective

Primary objective of the study is to determine whether prolonged use of 96 hours leads to growth of microorganisms (type and numbers (CFU/ml)) in enteral tube feeding sets. Secondary objectives are the occurrence of gastrointestinal events/ new onset of sepsis, the effect of Selective Digestive Decontamination (SDD) on the growth of microorganisms and the durability of the enteral tube feeding sets when used for 96hrs.

### Study design

A monocenter exploratory pilot safety trial

### Intervention

Extended use of an enteral tube feeding set from 24 hours to 96 hours

### Study burden and risks

Risk of this study concerns the potential growth of pathogenic microorganisms in the enteral tube feeding system. The actual growth of pathogenic microorganisms cannot be monitored, because findings of the microbiological cultures take around 2-7 days to arrive, depending on the type and amount of microorganisms. This suggests that pathogens may be growing with negative health issues for the patient as a result

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Mentally competent
Age 18 years or older
Treatment with continuous enteral feed is expected to last for at least 96hrs from inclusion (minimum 20ml/hr)
Gastric/ jejunal tube inserted during current hospital admission
ICU patients: treated with Selective Digestive Decontamination (SDD) which implies expected mechanical ventilation for more than 48 hours.

## Exclusion criteria

Inability to feed enteral due to gastro-intestinal disease
Patients with severe gastro-enteritis (according to doctor*s opinion), chronic abdominal bowel disease
Patients with immune system disorders
Palliative care

# Study design

## Design

**Study type:** Interventional

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Health services research |

## Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-02-2025 |
| Enrollment: | 45 |
| Type: | Anticipated |

## Medical products/devices used

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|---|---|
| Generic name: | Flocare Enteral Feeding Sets (ENFit) |
| Registration: | Yes - CE intended use |

# Ethics review

Approved WMO

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| Date: | 12-12-2024 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

# 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 | NL87418.100.24 |