

FMT compassionate use

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Background

The use of FMT (Faecal Microbiota Transplantation) is described in the national Danish clinical guideline.¹ There may be specific clinical situations where use outside of established indications is considered justified, considering the overall treatment of the patient, and where the medical assessment is that the benefits outweigh the risks.

Compassionate use may occur based on an *individualised healing attempt*, as defined in Article 37 of the World Medical Association's Declaration of Helsinki¹. Compassionate use is defined by the European Medicines Agency as “use of an unauthorised medicine outside a clinical study in individual patients under strictly controlled conditions.”

Principles for Use

Three principles should be met when considering FMT (European expert consensus, unpublished):

1. The clinical condition prompting the consideration of FMT should be related to an affected gut microbiome.
2. The use of FMT should be supported by a biological rationale and, if possible, experimental evidence.
3. The decision should be made by a defined expert panel, weighing the benefits and risks.

Compassionate use should be accompanied by documented patient consent, clinical follow-up, and registration of effects or adverse events.² The assessment of benefits and risks should be documented in the patient record, along with the overall evaluation. Before treatment, the duration and clinical treatment goal should be agreed upon with the patient. The responsibility for treatment and follow-up lies with the prescribing physician. The case should preferably be published as a scientific paper.

Decision on the use of FMT

The decision regarding treatment is made at the IBD conference in LMT, documented in the patient record, and registered in CEFTA as an event (compassionate use).

Inspiration: BSG Draft Guidanceⁱⁱ

Compassionate Use of FMT:

9.1: Consider offering compassionate use of FMT in non-*C. difficile* infection settings after discussion and approval in a multidisciplinary team setting.

9.2: When offering compassionate use of FMT, the following conditions must be met:

- There is a biological rationale to justify consideration.
- The patient is at risk of significant clinical compromise due to a limited range of alternative therapeutic options.
- The patient understands the risks and benefits of FMT compared to other treatment options.

9.3: Prior to treatment, define what will be considered a success or failure of FMT.

9.4: Prior to treatment, agree on a potential strategy for further FMTs based on initial clinical success.

ⁱ <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

ⁱⁱ <https://www.his.org.uk/news/fmt/>

References

1. Baunwall SMD, Dahlerup JF, Engberg JH, et al. Danish national guideline for the treatment of *Clostridioides difficile* infection and use of faecal microbiota transplantation (FMT). *Scand J Gastroenterol* 2021;56:1056-1077.
2. Whitfield K, Huemer KH, Winter D, et al. Compassionate use of interventions: results of a European Clinical Research Infrastructures Network (ECRIN) survey of ten European countries. *Trials* 2010;11:104.

ⁱ <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

ⁱⁱ <https://www.his.org.uk/news/fmt/>