Stool samples –

Efficient sampling

Protocol overview

Project title Stool samples - efficient sampling

Clinical trial design Proof of concept

Timetable November 2020 – December 2023

Purpose Testing of collection tubes for stool samples

Number of patients 50

Latest approval sep 14 2022

Summary

Several patients are admitted to the Oncology ward O81 and the medical department SUH, Køge (here primarily to rule out infectious diarrhea) with thin stools/diarrhea, which can be both chemo-induced and infectious and thus require isolation.

Patients who need to have a stool sample taken for microbiological examination risk receiving relevant treatment later if they cannot separate urine and stool. By waiting for a usable stool sample, the patient risks being hospitalized for a longer period of time and receiving relevant treatment with antibiotics or antidiarrheal agents later. In addition, there is a risk that any infection will be spread to other patients on the ward.

By developing a collection tube, the patient can have a stool sample taken upon arrival at the department and then receive relevant treatment when there is a response from the Microbiology Department. Resources can be saved on both isolation remedies and personnel if the patient is not diagnosed with a diagnosis requiring isolation.

In addition to the above, there is also the hygienic aspect that with the current remedies available, the staff must collect the stool sample from a basin and put it into a test tube that can be sent to the Microbiology Department. With the collection tube, it is possible to take the sample directly from the rectum.

With the completion of this study, it is expected that patients admitted with loose stools/diarrhea will be diagnosed more quickly and thus receive relevant treatment more quickly. This may lead to a shorter hospitalization period and savings on the resources that Zealand University Hospital uses on medicine, isolation measures and personnel.

The above method can be expected to be extended to other specialties than just oncology, as well as to the primary sector.

Background

Clinically, diarrhea is defined as three or more loose stools per day or an increased volume of stool (over 200 grams) per day. Diarrhea is divided into acute diarrhea, lasting less than two weeks, and chronic diarrhea, lasting more than two weeks. Diarrhea is defined based on the consistency, amount, appearance, and frequency of the stool [1]

Problem statement

Patients admitted with loose stools/diarrhea must be diagnosed quickly so that relevant treatment can be initiated. The current workflow of collecting stool samples from the pelvis without adding urine can extend the time to diagnosis and thus the hospitalization process, with the consequence that the patient will receive relevant treatment later.

Hypothesis

With a collection tube that can be easily inserted into the rectum, the time to collect the first usable stool sample will be shortened.

Purpose

Testing of collection tubes for stool samples.

Design

Proof of concept study, where the collection tube is tested on 50 hospitalized patients on Oncology Ward O81.

Inclusion criteria

- The patient must be at least 18 years old.
- The patient must be able to understand Danish
- All patients admitted to the Oncology ward O81 with loose stools/diarrhea. This is regardless of whether the patient is undergoing active medical cancer treatment and/or antibiotic treatment.
- It is a requirement that the patient is cognitively well-functioning and can understand the patient information related to the study.
- The patient must be able to cooperate optimally with the sampling itself. If this is not assessed at the time of admission, the patient will be excluded from the study.

Exclusion criteria

- Expected remaining life < 2 weeks

Recruitment

All patients admitted with loose stools/diarrhea will be offered the opportunity to participate in the study. They will be selected if they meet the inclusion criteria described above.

Procedures

Patients admitted with loose stools/diarrhea will have a stool sample taken with the collection tube at the time of admission.

The patient is placed on their side in a bed or on a stretcher before the actual sample collection.

The stool sample is then sent to the Microbiology Department for standard testing for Clostridium Difficile, pathogenic intestinal bacteria and viruses. No other analyses are performed and only the actual collection of the stool sample is included in the project. The stool sample taken with the collection tube replaces the stool sample with the standard method.

Method

In the current workflow for collecting stool samples, the patient must sign off with a stool sample on a basin. The stool must not be mixed with urine. The stool is then collected in a clear plastic container. A small spoon is attached to the brown lid of the plastic container and this is used to collect the stool in the plastic container. The lid is then screwed firmly onto the plastic container and it is marked with the patient's name and social security number from the PTB note. The plastic container is placed in the associated protective sleeve and sent for cultivation and resistance testing at the Microbiology Department.

If multiple samples are taken for the same examination, these must be taken from different stools, and if multiple samples are taken for different examinations, these can be taken from the same stool.

The method to be investigated in this study is the insertion of a collection tube into the rectum. The tube is passed 10 cm up the intestine. Then a spiral inside the collection tube is turned around and stool is collected in the tube, which is subsequently removed from the intestine again. The stool sample is now sealed inside the collection tube and the collection tube is marked with the patient's name and social security number from the PTB note. The collection tube is sent for culture and resistance determination at the Microbiology Department.

Experimental conditions: the subjects do not need to be specially prepared for the collection.

Microbiological analysis: cultivation and resistance testing of bacteria and viruses in stool samples. An amount of stool the size of a large pea or approximately 2 ml is used.

Static considerations

Since this is a proof -of -concept study and the results can only be divided into either successful or unsuccessful, 50 patients are considered a suitable number. No statistical calculation has been performed.

Timetable

Project start date: 01.11.20

Project end date: 31.06.23

Place

The study takes place at the Oncology Ward O81, Zealand University Hospital (SUH), Roskilde and the Medical Ward SUH, Køge.

Practical options

A patient room, bed or bed, collection tube, office facilities with access to the Health Platform must be used.

Rights

Nurse Anne-Dorte Krapper will be responsible for collecting and storing data supervised by professor, senior physician Jørn Herrstedt.

Research engineer Anders Ohlhues Baandrup will be responsible for the contact with the company that will produce the collection tube, and will be kept informed about the study.

Chief physician, clinical associate professor, PhD Lasse Bremholm Hansen will supervise the collection method itself and will be continuously informed about the study.

Anne-Dorte Krapper will introduce nursing staff on the wards to the study so that they can participate to a certain extent in the collection of stool samples.

Ethics

It is estimated that there will be no additional inconvenience for patients who have a stool sample taken with the collection tube compared to the inconvenience of the standard method. There will be no additional attendances, as all patients are already hospitalized with diarrhea.

It will take less time to complete the questionnaire.

The study will be submitted to the Danish Medicines Agency, the Regional Scientific Ethics Committee and data notification to Region Zealand and will not be initiated until relevant approvals are available.

Information and consent

Patients included in the study will be informed verbally about the study at the time of admission and will be given written patient information about the purpose of the study. In this connection, the patient's immediate consent to participate in the study will be obtained.

The patient's consent gives the trial director, sponsor and sponsor's representatives, as well as any supervisory authority, direct access to obtain information in the patient's medical record, etc., including electronic medical records, in order to view information about the subject's health conditions, which is necessary as part of the implementation of the research project and for control purposes, including self-control, quality control and monitoring, which they are obliged to perform.

Data

Data is entered into Excel.

Data storage

Data is stored in pseudonymized form on PC, as all patients are assigned an allocation number. The allocation number ensures that no personally identifiable data is stored on PC. Backup files are placed in a locked filing cabinet in the department management office, and can be used to identify the patient.

Data will be stored in accordance with applicable regulations for trials, and destroyed thereafter.

The following patient data is collected:

Age, gender, cancer diagnosis, temperature (> 38.5), neutrophil count (< 0.5 x 10 9 /l), number of bowel movements in the last 24 hours, possible constipation in the last 24 hours, date of last series and type of medical cancer treatment (if applicable), date of hospitalization, date of stool sample and results of stool sample.

The above patient record information must be used to ensure that these are relevant patients in terms of being hospitalized with infectious diarrhea, as well as to describe demographics and any comorbidity.

The information that will be used in the project before consent is given from the subjects is passed on to the researcher.

The experiment has been registered with Region Zealand and is subject to the Data Protection Act and the General Data Protection Regulation .

Economy

The study is supported by the Department of Clinical Oncology and the Innovation and Technology Council at Zealand University Hospital with Match Point funding of DKK 100,000.

MatchPoint is a project under Zealand University Hospital, where innovation projects, after a professional assessment, are financially supported with DKK 100,000 for development and testing.

MatchPoint funds: DKK 100,000.

The above has financed the development of collection tubes, patent search and salaries.

Funding: the experimental group has received an Inno Explorer grant, funding the study.

There are no affiliations with any companies with an interest in the trial, among any of the participants in the trial group. The study is part of a product development, and there is no product on the market at present. A number of prototypes will be manufactured, paid for by the trial group, with funds from MatchPoint allocated to the group.

The research group has no financial interest in the study, but wishes to patent the invention.

Recruitment of subjects and informed consent

The subjects are recruited at the time of admission when the doctor records the admission record and prescribes that stool samples be taken for culture and resistance testing. The patient will be isolated and will thus be alone in a patient room, so that oral information and conversation about the study and its rationale can take place undisturbed. Written patient information will be provided.

The right to an assistant will be offered when a potential candidate for the study is identified.

Since the purpose of the study is a quick and efficient collection of stool from the rectum, where we have the opportunity to reduce the time in isolation, we want the reflection time to be reduced as much as possible, preferably to 1-2 hours, and since the experiment is considered completely harmless and will not impair treatment, this is considered reasonable.

The patient's immediate consent to participate in the study is obtained as soon as a prescription from a doctor is available and the patient has given his consent after a period of reflection.

Publication of results

As it is a proof of concept study, the results will be used to develop a larger study.

Trial results of both positive, negative and inconclusive grades will be published.

Administrative matters

- Notification/approval to the Danish Medicines Agency
- Notification/approval to the Regional Research Ethics Committee
- Data notification/approval to Region Zealand
- Security
- Insurance: Patients are covered by the hospital's general patient insurance.
- Division of responsibilities
- Publication – journal

Reference list

Fernández-Bañares F. et al: æChronic diarrhoea : Definition, classification and diagnosis. Elsevier, Gastroenterol Hepatol . 2016;39(8): 535-559

Layman's summary

The purpose of this study is to collect a stool sample from the patient who is admitted with loose stools/diarrhea, already at the time of admission.

The study is not considered to be associated with any risks or disadvantages for the patients who participate.