

Title:

Patient Empowerment: Web-based Monitoring in Children and Adolescents With Inflammatory Bowel Disease for Better Quality of Treatment

ClinicalTrials.gov Identifier: NCT01860651. Registered May 2013

Danish Ethical Committee: Journal number H- 2-2013-061),

Danish Data Protection Agency: Journal number HVH-2014-004)

Date: June 24, 2013, updated November 3, 2017

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STUDY PROTOCOL

Hypothesis

Adherence to medicine in young chronic patients is low and difficult to achieve. It is our hypothesis, that adherence can be optimized by integrating young patients with chronic inflammatory bowel diseases (IBD), in their own disease course and support their empowerment by using an E-health web-based monitoring.

Background

The two inflammatory bowel diseases, Ulcerative Colitis (UC) and Crohn's Disease (CD), constitute the majority of IBD. In Denmark the prevalence of IBD is approximately 35.000 patients and 10-15 % is pediatric patients.

E-health

Previous studies have used E-health in the treatment of adult IBD patient: In one study including 300 patients with mild-to-moderate ulcerative colitis (UC), E-health treatment resulted in shortening periods of active disease (average 18 vs. 77 days in the control group). 88% were satisfied with their treatment using E-health and the need for outpatient visits was reduced[1]. In another study on 27 patients with CD treated with biologicals, E-Health was able to optimize the timing of the infusion of infliximab according to the disease activity, resulting in longer periods between the infusions[2]. The E-health solution was safe and patients demonstrated an adherence to the program of 86%. To our knowledge no study has previously used E-health treatment in adolescence with IBD. E-health is probably even better accepted by this group of patients, as web communication is a wellintegrated part of young patients daily lives.

Clinical relevance at different levels

Individual

By involving patients in their own treatment through education and by the use of the E-health program it is expected to increase the patient adherence and empowerment and thereby to ensure treatment quality. The interaction between patient and doctor through the E-health program is expected to provide a more continuous disease handling without delays and increase patient satisfaction. Since "web-rounds" (doctor checking the patient's web-site) do not require the presence of patient and doctor at the same time, the patients avoid taking time off from school/education/work to attend the out-patient clinic for control visits when their disease is in remission.

Departments

Using the E-health program for disease monitoring will create the opportunity to reorganize the treatment of patients with chronic diseases. Avoiding "unnecessary" outpatient visits when the disease is in remission will make it possible to concentrate on consultations when the disease is active. Web-rounds are part of the *DRG registration* (economic system between government, regions and departments).

Aim

Through E-health intervention to

- Increase patient's own responsibility for the treatment and thereby better adherence and support patient empowerment
- Reduce patient's:
 - i) Disease activity
 - ii) Need for surgery
 - iii) Days of absence from school

- v) Need for outpatient visits
and
VI) Optimize the timing of infliximab treatment.

Study design

The study consists of two projects:

Study 1 (for the following: *Project Web-Home-Med*): A prospective study including IBD patients treated with non-biological treatment. Patients will be randomized to an *E-health* group or control group.

Study 2 (for the following: *Project Web-Biologicals*) : A prospective descriptive study including IBD patients treated with biological infusions (Infliximab). The participations have to use an E-health program in order to optimize the timing of infusions.

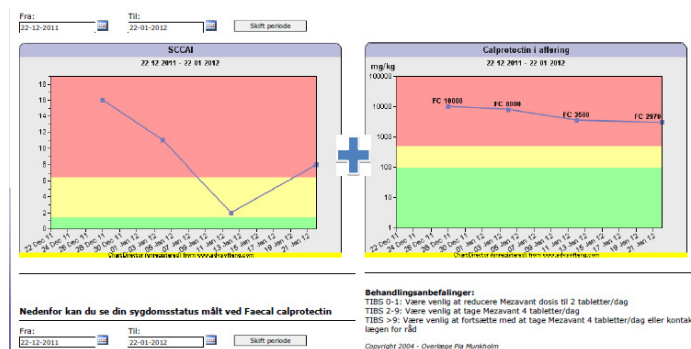
E-health

Using the E-health program consists of following:

- An education lesson about the disease and how to use the web-programme
- Registering symptoms through validated disease activity indexes
- Sending in fecal samples for analysis of fecal calprotectin (FC)
- Deliver blood test
- Filling out questionnaires about: self-rated adherence, status of health, days of absence from school and hospitalizations

The E-health web-program is monitored by the project physician and patients' records are assessed, ensuring the appropriate follow-up. In the E-health program the symptom scores are presented to the patient via a simple traffic light chart and demonstrate the course of disease activity over time. Figure 1

Figure 1.Example from adult constant-care.dk



The study will be performed at the Pediatric Department, Hvidovre University Hospital and include IBD patients aged 10-17 years. The patient will be followed for two years.

Project description:

Project Web-Home-Med E-health group and Project Web-Biologicals

The E-health intervention consists of education about the disease and about use of the web-program. E-health group, project *Web-Home-Med* also includes an annual consultation at an IBD center.

Education

Patients and their parents will be informed about the disease and how to use the web-program during an one hour information session. The participant learns about the symptoms of active disease and how they must be registered in the web program. Patients are instructed to consult a doctor if they have any of the following alarm symptoms:

- More than six stools per day
- Daily fresh blood in the stool (at each defecation)
- Fever (temperature > 37.5 ° C)
- Severe abdominal pain and / or tenderness
- Acute to severe exacerbation of symptoms.

Patients are reminded that there are no restrictions on contacting their doctor, if the need arises.

E-health intervention

Each participating patient will receive a username and password to log on to the web-program. All personal data will be kept under secure conditions in accordance with the Danish Data Protection Agency's rules and only the physician related to the project will have access to the personal data. The personal website indicates which forms the participant must complete.

Registering symptoms

The web-program requires that the participants complete disease activity scores: Pediatric Ulcerative Colitis Activity Index (PUCAI)[3] for UC patients and abbreviated Pediatric Crohn's Disease Activity Index (aPCDAI)[4] for CD patients.

The scores from PUCAI and aPCDAI are presented to the patient via a simple traffic light chart which shows whether the patient, depending on the severity of disease activity, is in the green (mild), yellow (moderate) or red (severe) zone. On the chart, the participants can see the course of disease activity over time. In Project *Web-Home-Med*, participants must register symptoms every four weeks, in Project *Web-Biologicals*, they must do so weekly for the first four weeks after infliximab treatment.

Fecal calprotectin

In project *Web-Home-Me.*, the patients will be asked to take a stool sample for FC at baseline and thereafter every three months. If disease activity is worsening, i.e. the patient is in the yellow or red traffic light zones, extra FC analysis will be needed. In project *Web-Biologicals*, patients will be asked to send in fecal samples for FC analysis four weeks after infliximab treatment and weekly thereafter.

The laboratory performs all FC analysis and enters the results in the web-program so that both patient and doctor are informed about the FC level. Scores from PUCAI and PCDAI will be added with FC scores to yield the total inflammations score (TIBS), which will be presented as a traffic light colour as well.

Blood tests

Every three months participants in Project *Web-Home-Med*. are asked to take a routine blood test at either a local laboratory or at Hvidovre University Hospital. Blood samples are similar to the standard IBD-package

of blood tests with which laboratories are already familiar. For patients in Project *Web-Biologicals*, the routine blood samples are taken prior to infliximab infusion.

Blood test results will be reviewed by the project physician and compared with symptom scores on the web-program. Both the effects of the treatment and the side effects, in the form of bone marrow suppression, will be evaluated. If the patient's blood test results fall outside the acceptable limits, the patient will be contacted by telephone for a consultation with a pediatric specialist. Blood sample results within acceptable limits will be indicated on the patient's personal web page. In project *Web-Biologicals* Infliximab concentration and antibodies will be measured as well.

Self-rated adherence and Quality of life

Participants in Project *Web-Home-Med.* must assess their adherence to treatment using a Medicine Adherence Report Scale (MARS)[5] and a Visual Analog Scale (VAS). VAS is a 10 cm long line, representing the spectrum from always taking medicine to never. The patients have to set a mark representing how often they take the medicine.

To assess the patient's quality of life, participants in both projects completes the "IMPACT III" questionnaire (questionnaire for children and young people about general condition). IMPACT III is developed by the *Pediatric Inflammatory Bowel Disease Working Group on Quality of life* represented by Dr. Anthony Otley, Canada [6]. Through cooperation with the *Quality of life group* the questionnaire is certificated in Danish after a cross-cultural adaptation, including a forward and backward translation and a cognitive debriefing (validation of the questions).

MARS, VAS and IMPACT III have to be entered every three months in project *Web-Home-Med.* and every four week plus before the infusion of infliximab, in project *Web-Biologicals*,

Web-rounds

The web-program is monitored by the project physician and patients' records are assessed. If a patient's symptoms progresses to the yellow or red zones, the website advises the patient to send in a stool sample for FC analysis. If the patient are in severe and moderate disease activity (the yellow and red zone), they are requested to contact the project physician. The patient will be contacted by the project physician, if the patient does not contact the physician, to ensure appropriate follow-up.

If a patient progresses to the yellow or red zones in project *Web-Biologicals*, the patient will be contacted by the project physician and will be offered infliximab treatment within a few days. If the patient remains in the green zone, infliximab treatment will postponed for a maximum period of 12 weeks.

Registration of medical treatment

On the web-program, participants in project *Web-Home-Med* register their prescribed medication. In project *Web-Biologicals*, only infliximab treatments are registered, as patients' other medical treatment remains unchanged during the project.

Reminder

Patients are reminded every four weeks or weekly (depending on the project) via SMS to log on to the web program for symptom scoring, as well as when they need to give blood samples or submit stool samples.

Smartphone

The web-program is also designed for use on smart phones, and is therefore easily integrated into the patient's daily life.

Project Web-Home-Med, annual control at IBD-center

Once a year, the patients will have a prolonged consultation (two or three hours) at the IBD center, during which patients will be thoroughly examined by a pediatric gastroenterology specialist and IBD-nurses.

Project Web-Biologicals, treatment

Treatment is initiated if the patient has active disease or a maximum of 12 treatment-free weeks have occurred. The initiated treatment follows the usual guidelines for IBD treatment.

Contact

Patients are informed that they can call or send an e-mail to the project physician if they need additional support or information. Patients are in no way discouraged from using the emergency medical contact if they feel it necessary.

Project Web-Home-Med: control group

Patients randomized for the control group follow the usual guidelines with visits in the out-patient clinic every third month. At each consultation blood samples will be taken and patients asked to bring a fecal test for FC analysis. In addition to the usual control visits, patients complete forms adherence (VAS and MARS) and quality of life (IMPACT). Furthermore they will be asked to keep track of the number of lost school days per month and what medications they currently take. The questionnaires are completed in the clinic.

Collection of data from prescription database and electronic patient file (e-journal).

Information from the prescription database is obtained to check whether the prescribed medication is collected by the patients. Any hospitalization is recorded by the doctor in the e-journal.

STATISTICAL ANALYSIS PLAN

Project A (*Project Web-Home-Med*):

Power calculation was made on the basis of a mean Medication Adherence Report Scale (MARS) score of 20,67; SD 4,01[5]. Using a power of 80%, a significance level of 5%, and an actual difference of 3 on the MARS scale, 58 participants were needed.

Results:

Data were analyzed as intention to treat. Because of the non-parametric distribution of outpatient visits and hospitalizations the Wilcoxon sum rank test was used to compare the web and control group. T-test was used to compare absence from school between the two groups. To account for the longitudinally-collected data, alterations during the observed period comparing the web and control group regarding disease activity (symptom score, blood test and FC) and medical adherence were analyzed using a mixed effect model (MEM). MEM models included a random patient effect and a fixed effect interaction between group and time, to evaluate difference between the groups over time. Further adjustment variables that were included are listed below for the specific models. Time to drop out, first on-demand visit, and step-up in treatment were analyzed by Kaplan Meier survival analysis. P-value <0.05 was considered as significant.

Project B (*Project Web-Biologicals*):

Results:

Demographic values and treatments, and blood samples were described by frequency (percent), median (range), and mean (SD). To account for the repeated measures, Mixed Effect Models (MEM) were used to compare the eHealth and control groups regarding lengths of treatment intervals, IFX doses, and IFX trough concentrations. The association between IFX concentration and treatment intervals was also analyzed by MEM. Comparison of the number of patients developing antibodies to IFX was analyzed by Fisher's exact test. The first and final HRQoL score for each patient were compared using a paired t-test. *p* values <0.05 were considered as significant.

Statistical analyses were performed using SAS Enterprise Guide 7.1 and the statistical computing program R 3.2.2, R Core Team 2015 (R: A language and environment for statistical computing, R Foundation for Statistical Computing, Vienna, Austria. URL <https://www.R-project.org/>).

Ethical issues

The trial was approved by the Danish Ethical Committee (Jr. H- 2-2013-061) and the Danish Data Protection Agency (Jr. HVH-2014-004). It was registered on www.clinicaltrials.gov in May 2013 (ClinicalTrials.gov Identifier: NCT01860651). All patients and their guardians gave oral and written consent prior to their inclusion in the study.

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Carlsen K., Jakobsen C., Houen G., Kallemose T., Paerregaard A., Riis LB., Munkholm P., Wewer V. Self-managed eHealth Disease Monitoring in Children and Adolescents with Inflammatory Bowel Disease: A Randomized Controlled Trial. *Inflamm Bowel Dis* 2017; 23(3): 357–65. Doi: 10.1097/MIB.0000000000001026

Carlsen K., Jakobsen C., Hansen L., Paerregaard A., Munkholm P., Wewer V. Personalized infliximab treatment of adolescents with inflammatory bowel disease. *J Crohn's Colitis* 2014; 8(Conference Publication: (var.pagings). 8 (pp): s408. Doi: 10.1017/CBO9781107415324.004.

INFORMED CONSENT FORM (A)

Patient Empowerment: Web-based Monitoring in Children and Adolescents With Inflammatory Bowel Disease for Better Quality of Treatment

Project A (Project Web-Home-Med)

Purpose of the project

The aim of the project is to ensure better treatment for children and adolescents with inflammatory bowel disease, i.e. patients who have one of the two diseases: Crohn's disease or Colitis Ulcerosa.

Our aim is through the E-health intervention to

- Increase patient's own responsibility for the treatment and thereby better adherence and support patient empowerment
- Reduce a patient's:
 - i) Disease activity
 - ii) Need for surgery
 - iii) Days of absence from school and
 - v) Need for outpatient visits

We will try to achieve the goals by using a personal website for young patients with inflammatory bowel disease.

Randomization and distribution in groups

Since it is a scientific experiment, it is necessary to have a group that tests the website and a group following the usual treatment. The groups are compared and this is important in order to determine if it helps to use the website. Therefore, your son/daughter will, if he/she chooses to participate in the trial, participate in a random draw, to be followed by a web group or a control group. It is equally important for the experiment whether your child is in one or another group.

We hope to include 70 patients in the project, ie. 35 participants in each group, all aged 10-17 years. Below are the procedures described in the web group and the control group, respectively. Will we follow the participants this way for two years.

Usefulness of the experiment

By participating in the experiment, whether your child is in the web or control group, your child will in future help other children and adolescents with inflammatory bowel diseases as we hope to ensure treatment quality.

Risks, side effects and disadvantages

Overall, there is no risk associated with participation in the project. There are no risks involved in taking bowel tests, nor are there any risks associated with blood sampling. Personal information will be stored on a secure computer that is subject to the Data Inspectorate's rules and complies with the applicable law on the processing of personal data. Users of the system, patients or patient's doctor (if the doctor has patient acceptance) may at any time request their personal data deleted.

Exclusion and discontinuation of tests

It is voluntary to participate in the trial. You may, at any time and without giving a reason, withdraw your consent for your child's participation in the project. It will not affect your child's further treatment.

The website has been tested on adult patients without any security issues when using the disease monitoring website. Therefore, we do not expect circumstances to arise that can lead to the interruption of the experiment. If the project should cause harmful effects, the project will be completed and you will be informed accordingly.

Consent for your child's participation in the trial involves giving you access to the relevant authorities as part of their control of the trial, obtaining necessary information about the health status of the subject. The authorities are subject to secrecy.

If your child is randomized to the web group:

The web group uses a personal website and each participant is assigned a personal login and password. On the website your son/daughter must record symptoms. Answers from bowel tests and blood tests are also included. The website is structured as a three-color scheme: red, yellow green, as a traffic light, and represents severe, medium and mild level of disease activity.

When symptoms are entered, the computer shows whether your child's disease activity is similar to severe, medium or mild disease activity. Along with responses to bowel tests, the computer calculates how active the disease is. As your child scores his symptoms, a curve will show the disease activity over time. Your son/daughter can thus keep track of how activity in the disease develops. Depending on whether the graph moves in green, yellow or red zone, the following must be done:

Green: Continue the ongoing treatment

Yellow: Call a doctor

Red: Call a doctor and order a time to get in control of the day hospital

Another aim of using the website is to make your child aware that he/she must remember to take his/her medication. We know it's hard to remember to take medicine every day. With the website it becomes clear that you should take your medicine, as it is important to maintain the disease activity in green areas.

Plan of the experiment and what should your child do:

The trial will continue for 2 years. You will initially be invited to a meeting with a project doctor who will teach your child to use the website and explain what symptoms you should be aware of. After your son/daughter has learned how to use the website, the participation can start.

Symptoms and Health: Your child must enter his/her symptoms once a month and answer questions about his overall health every three months.

Blood tests: Your child must have taken blood samples every 3 months. Blood samples are taken at the laboratory that you usually use, and the same tests are taken as during normal treatment. There will be deprived 18 ml of blood.

Fecal tests: Every 3 months a feces test for inflammation should be submitted. A "easy-sampler-set" is provided for use to take the stool test. This includes gloves, plastic pipes and a piece of paper that can be put on the toilet that keeps the stool. After the sample has been removed, the paper can be flushed in the toilet. The quantity of the fecal sample should size a hazelnut (equivalent to 10 grams.)

SMS reminder: A text message will be sent to your son/daughter with a reminder of when to enter symptoms, submit a bowel test and to take blood samples.

Medicine intake: In a schedule, your son/daughter marks how adherent to the medicine he/she thinks he/she is.

Health, well-being and hospitalization: Every 3 months a schedule regarding your child's general health and well-being needs to be completed. Furthermore, the number of school absence days and whether there have been any hospitalizations. If there have been hospitalizations, a doctor will gather information from your child's journal on when, for how long and for what reason, the hospitalization expired.

Only your child, you and the doctor have access to the website. The doctor has access to follow the symptoms so that you can contact you if necessary. You can always contact a doctor or other doctor if necessary and acute deterioration.

As this is the first time we use the website, we will also ask your son/daughter about how it was to use the website and whether it should be changed. Since there are upcoming patients who have the same illness and age as your child who needs the website, the answers will be useful for the further development of the website.

Smartphones

The web page is made feasible to smartphones, which allows your child to enter symptoms regardless of where he/she is. We want to make it as easy for your child as possible to use the program.

Follow up once a year in the IBD center

Once a year, your child will be seen in the IBD center for a 2-3 hour continuous check. Here your child will be seen by both a nurse and a doctor.

Handling of biological material

All biological material, i.e. blood and bowel tests will be linked to a participant number, that is, all samples will be encoded but can be relegated to the relevant CPR number by project physicians if necessary. When data will be analyzed and presented, it is after coded data, why personal information will not appear. Blood samples are analyzed immediately as soon as the laboratories receive the samples and material that is not used will be destroyed. Excessive feces are stored in a biobank for later scientific research. The samples are encoded by participant number so personal information is not displayed.

10 years after end of the study, all data and samples from the project will be destroyed.

However, if you do not want your child to participate in the project, he/she may be destroyed if you wish.

If your child comes in the control group:

If your child is assigned to participate in the control group, you will be monitored with regular follow ups at the hospital every three months. In connection with the controls, your child need to deliver blood and fecal tests. When you meet up for in the clinic, we will ask your son/daughter to fill out the forms of general health and number of school days missed due to the illness. In addition in a schedule, your son/daughter marks how adherent to the medicine he/she thinks he/she is. The doctor who sees your child for the check-up time, does not know what your child is responding on the adherence schedules.

Information about economic conditions

The website is founded on the idea of professor Pia Munkholm, consultant in adult gastrointestinal diseases, Herlev Hospital. The project is organized by PhD student Katrine Carlsen with close guidance from senior consultant in pediatrics, Vibeke Wewer and consultant Pia Munkholm. Trial manager is not affiliated with support providers.

The project is covered by mutual funds and is supported by: European Crohn's and Colitis Organization, Queen Louise's Hospital Foundation, Tryg Foundation, CALPRO A/S, Tillotts Pharma, Capital Region Denmark, Alice and Frimodts Foundation, Ulcerative Colitis and Crohn's Danish Patient Society, MSD, and Promonitor/Orion Diagnostica.

Access to experimental results

Ongoing results from the project will be presented at the annual family home evening at the IBD Center at Hvidovre Hospital, where you are welcome to come and hear about the project. In addition, the results of the trial will continuously be printed in international journals, as well as presented at international and national congresses. All data from participants will be anonymized, which means that participants in the project cannot be identified. The trial will be completed in January 2016, after which data will be analyzed and described.

More information

In addition to this written information, we will also provide you with oral information about the project. This, you will be invited to if you are interested in participating. If you would like to know more about the experiment, please feel free to contact us at the contact details below. You must sign a permit for your child to be part of the project. We need a signature from both mother and father. We also ask you to read the last page for "The subject's rights in a health science research."

INFORMED CONSENT FORM (B)

Patient Empowerment: Web-based Monitoring in Children and Adolescents With Inflammatory Bowel Disease for Better Quality of Treatment

Project B (Project Web-Biologicals)

Purpose of the project

The aim of the project is to optimize the treatment with biological drug (Infliximab). The aim is to time the infusions when it is most appropriate in relation to the disease activity. This means that treatments can be given before 8 weeks or up to a maximum of 12 weeks apart.

We will ensure this timing, by following the symptoms and inflammation of feces continuously through a web program, to provide treatment as soon as there is a progress in the disease activity.

Usefulness of the experiment and number of participants

By participating in the experiment, your child will in future help other children and adolescents with inflammatory bowel disease. We hope to get 25 participants in the trial.

Risks, side effects and disadvantages

Overall, there is no risk associated with participation in the project. There are no risks associated with abduction tests, nor are there any risks associated with blood sampling. Personal information will be stored on a secure computer that is subject to the Data Inspectorate's rules and complies with the applicable law on the processing of personal data. Users of the system, patients or patient's doctor (if the doctor has patient acceptance) may at any time request their personal data deleted.

Exclusion and discontinuation of tests

It is voluntary to participate in the trial. You may, at any time and without giving a reason, withdraw your consent for your child's participation in the project. It will not affect your child's further treatment.

The website has been tested on adult patients without any security issues when using the disease monitoring website. Therefore, we do not expect circumstances to arise that can lead to the interruption of the experiment. If the project should cause harmful effects, the project will be completed and you will be informed accordingly.

Consent for your child's participation in the trial involves giving you access to the relevant authorities as part of their control of the trial, obtaining necessary information about the health status of the subject. The authorities are subject to secrecy.

Web Program

The web program consists of a personal website and each participant is assigned a personal login and password. On the website, your son/daughter must record symptoms and answers from the fecal samples are recorded from the laboratory.

The website is structured as a three-color scheme: red, yellow green, - as a traffic light corresponding to severe, medium or mild disease activity. The computer calculates how active your child's disease is by adding symptoms and fecal tests and the disease activity is depicted in the traffic light scheme. If your son/daughters disease activity is in yellow or red zone, it means he/she needs treatment.

Plan of the project and what should your child do:

The trial will continue for 2 years. You will initially be invited to a meeting with a project doctor who will teach your son/daughter in the use of the website and explain what symptoms you should be aware of. After your son/daughter has learned to use the website, the participation starts.

Symptoms and Health: Symptoms and questions about your health should be entered 4 weeks after treatment and then once a week until you receive treatment.

Fecal tests: A fecal test for inflammation should be submitted 4 weeks after a treatment, and then once a week for the next treatment. An “easy-sampler-set” is provided for use to sample the stool. The set includes gloves, plastic pipes and a piece of paper that can be put on the toilet that keeps the stool. After the sample has been removed, the paper can be flushed by the toilet. The quantity of the fecal sample should size a hazelnut (equivalent to 10 grams.)

SMS reminder: Your son / daughter will receive a text message with a reminder of when he/she has to enter symptoms and submit a stool sample.

Treatment: When activity occurs in your child's disease, corresponding to yellow or red area in the traffic light, he/she must receive treatment within three days. Therefore, you must contact the department and agree on time for treatment when activity occurs in the disease.

Blood tests: Prior to treatment, in relation to intravenous access, blood samples are deprived in the same way as usual when your child is to be treated. 18 ml of blood are removed. Blood will be analyzed for inflammations markers and effectiveness (concentration and antibodies) of the medication (infliximab).

Health, well-being and hospitalization: 5 weeks after treatment, as well as the day of treatment, a schedule regarding your child's overall health and well-being must be completed. In addition, the number of missed school days and whether there have been any extra out patients visits between each treatment. If there have been hospitalizations, a doctor will gather information from your child's journal on when, for how long and for what reason, the hospitalization expired.

Only your child, you and the doctor have access to the website. The doctor has access to follow the symptoms so that you can contact you if necessary. You can always contact a doctor or other doctor if necessary and acute deterioration.

As this is the first time we use the website, we will also ask your son/daughter about how it was to use the website and whether it should be changed. Since there are upcoming patients who have the same illness and age as your child who needs the website, the answers will be useful for the further development of the website.

Smartphones

The web page is made feasible to smartphones, which allows your child to enter symptoms regardless of where he/she is. We want to make it as easy for your child as possible to use the program.

Handling of biological material

All biological material, i.e. blood and bowel tests will be linked to a participant number, that is, all samples will be encoded but can be relegated to the relevant CPR number by project physicians if necessary. When data will be analyzed and presented, it is after coded data, why personal information will not appear.

Blood samples are analyzed immediately as soon as the laboratories receive the samples and material that is not used will be destroyed. Excessive feces are stored in a biobank for later scientific research. The samples are encoded by participant number so personal information is not displayed.

10 years after end of the study, all data and samples from the project will be destroyed.

However, if you do not want your child to participate in the project, he/she may be destroyed if you wish

Information about economic conditions

The website is founded on the idea of professor Pia Munkholm, consultant in adult gastrointestinal diseases, Herlev Hospital. The project is organized by PhD student Katrine Carlsen with close guidance from senior consultant in pediatrics, Vibeke Wewer and consultant Pia Munkholm. Trial manager is not affiliated with support providers.

The project is covered by mutual funds and is supported by: European Crohn's and Colitis Organization, Queen Louise's Hospital Foundation, Tryg Foundation, CALPRO A/S, Tillotts Pharma, Capital Region Denmark, Alice and Frimodts Foundation, Ulcerative Colitis and Crohn's Danish Patient Society, MSD, and Promonitor/Orion Diagnostica.

Access to experimental results

Ongoing results from the project will be presented at the annual family home evening at the IBD Center at Hvidovre Hospital, where you are welcome to come and hear about the project. In addition, the results of the trial will continuously be printed in international journals, as well as presented at international and national congresses. All data from participants will be anonymized, which means that participants in the project cannot be identified. The trial will be completed in January 2016, after which data will be analyzed and described.

More information

In addition to this written information, we will also provide you with oral information about the project. This, you will be invited to if you are interested in participating. If you would like to know more about the experiment, please feel free to contact us at the contact details below. You must sign a permit for your child to be part of the project. We need a signature from both mother and father. We also ask you to read the last page for "The subject's rights in a health science research."