Technetium-99m HMPAO granulocyte scintigraphy as a tool to measure inflammatory load in Ulcerative Colitis: a cross-sectional study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

Summary

ID

NL-OMON37564

Source
ToetsingOnline

Brief title
STATIC: Scintigraphy To Assess The Inflammatory load In ulcerative Colitis

Condition

- Gastrointestinal inflammatory conditions

Synonym
Inflammatory Bowel Diseasehttps://toetsingonline.ccmo.nl/ccmomon.nsf/0/A1A4F7B322EF7BF6C12579EC003742B8?EditDocument, Ulcerative Colitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Abbott,Abbott Laboratories

Intervention

Keyword: Inflammatory load, Technetium Scintigraphy, Ulcerative Colitis, WBC Scintigraphy

Outcome measures

Primary outcome

The main study parameter is the Summed Scintigraphic Activity Index (SSAI) of

WBC scintigraphy (in correlation with endoscopy/histology).

Secondary outcome

Secondary parameters are Mayo score by inclusion colonoscopy, biopsies, SCCAI

(Simple Clinical Colitis Activity Index), CRP, Albumine and thrombocyte count

and fecal calprotectin testing.

Study description

Background summary

Anti-TNF antibodies have become a generally accepted therapy for Inflammatory Bowel Disease (IBD), such as Ulcerative Colitis (UC). Nevertheless dose regimens remain arbitrary: a substantial part of patients lose their response to anti-TNF treatment. It is hypothesized that this loss of response is partly due to a fluctuation in inflammatory load, in which the optimal dose-response plateau is not yet reached.
A problem with dose-response studies is that the golden standard with regard to response, colonoscopy with biopsies, isn*t very suitable for frequent monitoring. Since patients experience colonoscopy as an uncomfortable and invasive examination and because it has some risks, especially in severe colitis (perforation), there*s a need for a different tool in assessing disease activity and response to therapy.
One, minimal invasive, instrument of determining inflammatory load is Technetium-99m Hexamethylpropyleneamine Oxime granulocyte scintigraphy (WBC

scintigraphy), which has been described for IBD in several studies before. But WBC scintigraphy hasn't been correlated with both colonscopy and inflammation markers such as CRP and fecal calprotectin for different severities of Ulcerative Colitis.
Moreover last decade imaging technique has been remarkably improved. Nowadays better gamma cameras and more precise labeling and cell isolation have been developed. Moreover the combination of scintigraphy with computed tomography (CT) scanning has enlarged its possibilities even more.
Therefore an updated study is necessary to determine the value of WBC scintigraphy in measuring inflammatory load in Ulcerative Colitis.

Study objective

The main objective is to validate WBC scintigraphy as a sensitive tool to measure and quantify inflammatory load in different severities of UC.
The secondary objectives are to explore whether other disease activity markers, like serum C-reactive protein (CRP) and fecal calprotectin are a representative reflection of inflammatory load.

Study design

The design of the study is a single center, prospective, cross-sectional study.

Study burden and risks

All patients will undergo blood and feces testing one time, 1 colonoscopy with biopsies (biopsies in the 2 endoscopically most affected areas of each of the 5 segments) and 1 WBC scintigraphy. Within 48 hours all of the examinations will be done, also a symptom scoring and physical examination will be performed.
Prior to scintigraphy, an 18G iv-line will be placed in an antecubital vein and 100 ml of blood will be drawn. From this, granulocytes will be isolated and labeled with technetium-99m. After labelling, the white blood cells will be reinjected intravenously through the same iv line. This procedure is identical to the validated clinical procedure of WBC scintigraphy.
200 MBq (0.011mSv/MBq) Tc-99m-labeled granulocytes will be reinjected in to the patient. The total amount of radiation will be approximately 4.0mSv.

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

-Age from 18 years, either male or female
-Established diagnosis (endoscopic/histological proven) of ulcerative colitis with different severities of disease and irrespective of treatment
-Clinical Indication for coloscopy for assessment of disease activity
-Obtained written informed consent
-A completed Truelove Witts Index

Exclusion criteria

-Toxic Megacolon, colon perforation
-Infectious disease (Positive stool culture)
-Pregnancy
-History of Colectomy
-Use of i.v. corticosteroids within the last 36 hours
-Renal Failure (eGFR<60)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-11-2012
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	22-10-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL39801.018.12