Haemostatic derangements after acute severe colitis and implications for duration of thromboprophylaxis.

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

Summary

ID

NL-OMON40875

Source
ToetsingOnline

Brief title
Haemostatic profile in ASC

Condition

- Gastrointestinal inflammatory conditions
- Embolism and thrombosis

Synonym
inflammatory bowel disease, Ulcerative colitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Enkel de 'consumables' worden gedekt door

grant van International Organisation for the Study of Inflammatory Bowel Disease Study Grant (IOIBD)

Intervention

Keyword: acute severe colitis, thromboprophylaxis, thrombosis, ulcerative colitis

Outcome measures

Primary outcome

To provide a comprehensive assessment of the haemostatic profile of patients

with acute severe colitis (ASC) during hospitalization and up to 12 weeks

post-discharge from hospital (page 12).

Secondary outcome

1. To identify biomarkers of a pro-thrombotic state in patients with ASC that

could be used to identify patients at highest risk of VTE, to guide the

duration of thromboprophylaxis and monitor response to treatment.

2. To inform the need for clinical studies of extended thromboprophylaxis for

patients with ASC after discharge from hospital

Study description

Background summary

Venous thromboembolism (VTE) is a disease specific extra-intestinal manifestation of Inflammatory Bowel Disease (IBD). Its mechanisms are poorly understood but are probably multifactorial with potentially fatal consequences. Whilst guidelines support the use of thromboprophylaxis in hospitalised patients with acute severe colitis (ASC), this is not advocated after discharge and population-based studies suggest that this may be the period of great risk for developing VTE. This study aims to provide a comprehensive assessment of global coagulation parameters in patients with ASC both in hospital and up to 12 weeks after discharge. The results will help define the period at risk for VTE and inform the rationale for clinical studies to examine the need for

extended thromboprophylaxis after discharge from hospital with ASC.

Study objective

This study aims to provide a comprehensive assessment of global coagulation parameters in patients with ASC both in hospital and up to 12 weeks after discharge. The results will help define the period at risk for VTE and inform the rationale for clinical studies to examine the need for extended thromboprophylaxis after discharge from hospital with ASC.

Study design

Prospective case-control study

Study burden and risks

Intervention: Blood sampling at day 1 and 5 of admission then at 4 week & weeks 8-12 post discharge clinic follow up, alongside routine blood sampling.

The risks of blood sampling are limited to potential bruising and discomfort at the site of venepuncture. The patient population is unlikely to have complications related to the extra volume of blood drawn. The 21ml blood draw (equivalent to two tablespoons), is minimal compared to the total circulating blood volume (~5 litres).

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

* Male or Female, aged 18 years or above;* Cases:
o Adult patients with ASC (Montreal S3 as defined by passage of *6 bloody stools daily with one or more of the following: heart rate *90 bpm, temperature * 37.8°C (99.5°F), haemoglobin level of <105g/L (10.5 g/dL), ESR *30 mm/hour or CRP*45;* Controls:
o Adult patients attending the outpatient setting with extensive UC (Montreal E3 as defined by involvement extending proximal to the splenic flexure) in clinical remission (Montreal S0, asymptomatic).;* Volunteers:
o Healthy adult volunteers with no history of IBD

Exclusion criteria

* Age < 18 years
* Previous history of VTE
* Known thrombophilia
* Anti-coagulant treatment
* Anti-platelet treatment
* Liver cirrhosis
* Recent thrombolytic therapy (<2 weeks)
* Antifibrinolytic treatment
* Pregnant or breastfeeding women

Study design

Design

Study type:	Observational invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-12-2014
Enrollment:	8
Type:	Actual

Ethics review

Approved WMO

Date:	24-09-2014
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	NL49897.018.14