

Pharmacokinetics of 6-thioguanine.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23696

Source

NTR

Brief title

N/A

Health condition

Crohn's disease of ulcerative colitis (IBD).

Sponsors and support

Primary sponsor: N/A

Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Determination of first pass effect of 6TG metabolites.

Secondary outcome

Determination of influence of different enzymes on 6TG metabolism.

Study description

Background summary

Patients will receive both 6TG orally and intravenously. On set times (for 8 hours) blood will be drawn to determine the concentrations of different metabolites and enzymes.

Study objective

Oral 6-thioguanine (6TG) results in a high intrahepatic exposure to 6TG generated metabolites.

Study design

N/A

Intervention

Blood draws.

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

1. IBD;
2. In need of immunosuppressants;
3. Intolerant to azathioprine or methotrexate.

Exclusion criteria

1. Concomittant use of drugs interfering with thiopurine metabolism;
2. Pregnancy/lactation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2005
Enrollment:	16
Type:	Actual

Ethics review

Positive opinion	
Date:	16-08-2005
Application type:	First submission

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
NTR-new	NL389
NTR-old	NTR429
Other	: N/A
ISRCTN	ISRCTN49579665

Study results

Summary results

N/A