TARC-002 EVALUATION OF THYMUS AND ACTIVATION REGULATED CHEMOKINE (TARC) IN PATIENTS WITH LYMPHADENOPATHY , FEVER OR NON-HODGKIN LYMPHOMA

Published: 10-04-2017
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To evaluate TARC in patients with fever, lymphadenopathy or non-Hodgkin lymphoma

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON45645

Source
ToetsingOnline

Brief title
TARC IN PATIENTS WITH LYMPHADENOPATH, FEVER OR NON-HODGKIN LYMPHOMA

Condition

- Other condition
- Lymphomas Hodgkin's disease
- Ancillary infectious topics

Synonym
Fever, lymph node enlargment, lymphoma

Health condition

andere ziekten gepaard met lymfeklier vergroting

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diagnostic, Hodgkin, Lymphadenopathy, TARC

Outcome measures

Primary outcome

Mean TARC levels (pg/mL) in correlation with final diagnosis.

Secondary outcome

Not applicable.

Study description

Background summary

Thymus and activation regulated chemokine (TARC) is elevated in about 90% of patients with classical Hodgkin lymphoma (cHL). TARC levels correspond with tumour volume and are used as a biomarker for treatment response. It is unclear whether TARC levels are also influenced by inflammatory states or can be elevated in patients with lymphadenopathy or other subtypes of lymphoma.

Study objective

To evaluate TARC in patients with fever, lymphadenopathy or non-Hodgkin lymphoma

Study design

This is a prospective study to determine TARC levels in patients with lymph node enlargement of unknown origin, fever and in patients who are already diagnosed with non-Hodgkin lymphoma subtypes. TARC levels will be matched with final diagnosis and compared with TARC levels of healthy controls and patients

with Hodgkin lymphoma, which have already been collected in previous studies.

Study burden and risks

Since this study only involves a single blood draw during routine diagnostic procedures there is no additional safety risk.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Age * 18 years;

- Ability to give written informed consent;
And one of the following:
(1) Lymph node enlargement of unknown cause for whicha diagnostic fine needle aspiration will be performedor
(2) Presenting with fever at the emergency department or
(3) Presenting with newly diagnosed or relapsed nodular lymphocyte predominant or non-Hodgkin lymphoma.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study (applicable to all subgroups):
- Ineligibility to give written informed consent;
- Patients with active atopic disease or hepatic failure;
- Patients already diagnosed with Hodgkin lymphoma

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):	17-05-2017
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	10-04-2017
Application type:	First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	NL59373.042.16
Other	nummer volgt