Study R-FACT
Risk factors for alloimmunization against red blood cell transfusions: a case cohort study

Published: 02-02-2010
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The aim of the project is to examine the association between clinical, environmental and genetic characteristics of the recipient of erythrocyte transfusions and the risk or resistance to immunization against erythrocyte alloantigens that he/she was...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Haemolyses and related conditions
Study type	Observational invasive

Summary

ID

NL-OMON44808

Source
ToetsingOnline

Brief title
R-FACT
Risk Factors for Alloimmunisation by red blood Cell Transfusions

Condition

- Haemolyses and related conditions

Synonym
red blood cell immunization, transfusion related hemolysis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: PPO-C Sanquin

Intervention

Keyword: alloimmunization, blood transfusion, case cohort

Outcome measures

Primary outcome

Our case-control study will quantify and characterize clinical risk factors of patients and conditions for transfusion associated alloimmunisation. Patients will be given a questionnaire to assess environmental and life style risk factors.

Blood sampling (upon informed consent) and buccal mucosal swabs will be carried out to determine genetic variation of immunization against red blood cell antigens.

Secondary outcome

-na-

Study description

Background summary

Alloantibodies can lead to serious clinical consequences and logistic problems like obtaining properly and timely matched blood for the patients who do develop these antibodies. Prevention of such serious events is possible by extended matching and typing of donor*s blood against the patient*s for all the possible antigens, but this process is cumbersome and costly. Identifying a high risk group will be a feasible first target for advanced matching a big step forward, and the aim of our study.

Study objective

The aim of the project is to examine the association between clinical, environmental and genetic characteristics of the recipient of erythrocyte transfusions and the risk or resistance to immunization against erythrocyte alloantigens that he/she was exposed to during that transfusion episode.

Study design

A retrospective case- cohort study will be performed.

Study burden and risks

Burden: the patients are asked to answer a short Questionnaire and one time Blood taking (= 25ml./ participant) or donation of 3 buccal musocal swabs.
Risk: Negligible, trained personnel involved in blood taking and handling.

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

- Patients for the first time diagnosed with transfusion dependent red blood cell alloantibodies (=patients who received transfusions before detection of alloantibodies).
- Patients who have been transfused, yet did not form red cell alloantibodies afterwards

Exclusion criteria

- Age below 18 years
- Patients with transfusions prior to the start of study inclusion period.

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:	Recruiting
Start date (anticipated):	01-09-2010
Enrollment:	1500
Type:	Actual

Ethics review

Approved WMO

Date:	02-02-2010

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	07-02-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	25-04-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	20-02-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	20-05-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	22-03-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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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	NL29563.058.09