Cytokine inhibition in Chronic Fatigue Syndrome patients - a pilot study

Published: 04-02-2014
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To investigate the effect on symptomatology of interference with IL-1 in CFS patients.

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

Summary

ID

NL-OMON40232

Source
ToetsingOnline

Brief title
CiCFS

Condition

- Other condition
- Immune disorders NEC

Synonym
chronic fatigue syndrome, myalgic encephalomyelitis

Health condition

chronisch vermoeidheidssyndroom

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Anonieme donor

Intervention

Keyword: Anakinra, Chronic Fatigue Syndrome, Cytokines, Intervention

Outcome measures

Primary outcome

The primary outcome measure will be fatigue severity measured with the Checklist Individual Strength (CIS).

Secondary outcome

Secondary outcome measures will be:

• level of functional impairment measured with the Sickness Impact Profile (SIP8) total score;

• physical and social functioning assesses with the subscale physical functioning and social functioning of the SF-36;

• level of psychological distress assessed with the total score on the Symptom Checklist-90 (SCL-90);

• pain severity assessed with a Visual Analog Scale (VAS);

• cytokine measurement in blood (plasma and blood in Pax-gene tubes) and salivary (at protein and mRNA level);

• cortisol measurement in salivary and hair;

• microbiome determination in faeces;

• body temperature and pulse rate.

Study description

Background summary

Chronic fatigue syndrome (CFS) is a medically unexplained syndrome for which no somatic or pharmacological treatment has been proven effective. Dysfunction of the cytokine network has been suspected to play a role in the pathophysiology of CFS. Although derangements of the cytokine network in CFS are controversial, a major problem is that many studies did not use adequate controls. In addition, all studies have been performed on peripheral venous blood of the patients. As cytokines mainly act in the tissues, e.g., the brain, the information that can be derived from peripheral blood cells is limited. The only information regarding a role of cytokines in pathophysiology could come from intervention studies in which pathogenetically important cytokines are inhibited. A potentially relevant cytokine which can be blocked in humans without severe side effects is IL-1.

Study objective

To investigate the effect on symptomatology of interference with IL-1 in CFS patients.

Study design

A randomized placebo controlled study will be performed to determine whether interference with IL-1 is able to reduce fatigue and disabilities in CFS patients.

Intervention

After inclusion patients will be randomized to receive one of the following treatments:
• the interleukin-1 inhibitor Anakinra (IL-1Ra) for 4 weeks (N=25);
• placebo for 4 weeks (N=25).

Study burden and risks

Burden:
• randomization between one of 2 treatment conditions and subsequent treatment (Anakinra or placebo for 4 weeks)
• pregnancy test at pretest evaluation;
• visit the ECCF at 0 weeks, at 4 weeks and (voluntary) at 6 months after inclusion;
• collection of blood samples at 0 and 4 weeks after inclusion (25mL);
• collection of saliva at 0 and 4 weeks after inclusion;
• collection of hair at 0 and 4 weeks after inclusion;
• submit faeces at 0 weeks after inclusion;
• bring a neighbourhood control at day 0;
• assessment of fatigue severity at pre-baseline screening, at day 0, week 2,3,4; thereafter monthly follow-up assessments up to 6 months after day 0;

• assessment of all secondary outcome measures (aside from pain) at day 0, week 4 and 6 months after a day 0;
• self-assessment of pulse rate weekly up until 4 weeks after inclusion, thereafter every month until the end of the study.
Risk:
• Possible side-effects of Anakinra: (transient) irritation at injection site, rarely development of neutropenia
Benefit:
• The possibility of an effective treatment of CFS in patients treated with ARA290 or Anakinra.

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

•CDC-diagnosed CFS-patients
•female, between 18 and 59 years old
•fatigue duration <=10 years, or significant increase of complaints during the last 10 years
•CIS (Checklist Individual Strength) >= 40
•marked functional impairment: Sickness Impact Profile (SIP-8) >= 700

Exclusion criteria

•pregnant or nursing women
•women who intent to get pregnant during the study
•fatigue duration >10 years
•patients who use or have used psychotropic medication in the past month
•substance abuse in the past 3 months
•patients taking any medication except oral contraceptives and/or paracetamol
•patients with evident somatic co-morbidity
•previous or current engagement in CFS research
•inability to understand the nature and the extent of the trial and the procedure required
•psychiatric co-morbidity (major depression, psychosis, eating disorders, anxiety disorders, bipolar disease and post traumatic stress disorder) assessed with the MINI
•live vaccination during the past four weeks
•current engagement in a legal procedure

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-08-2014
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Kineret
Generic name:	Anakinra
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	04-02-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-05-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-07-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-06-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-08-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2013-005466-19-NL
ClinicalTrials.gov	NCT02108210
CCMO	NL47571.091.14