The relation between muscle function and muscle pain in patients with chronic myeloid leukemia (CML): a pilot study

Published: 09-02-2017
Last updated: 14-04-2024

Primary Objective: To investigate whether differences exist in muscle function, muscle energy metabolism and cardiorespiratory fitness in CML patients with muscle complaints, compared to CML patients without muscle complaints, and controls (non-CML...

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

Summary

ID

NL-OMON43129

Source
ToetsingOnline

Brief title
CML and muscle function

Condition

- Muscle disorders

Synonym
The relation between muscle function and muscle pain in CML patients on TKIs, TKI-induced myopathy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: CML, muscle function, muscle pain, quality of life

Outcome measures

Primary outcome

Muscle function (= muscle force, contractile speed, relaxation, and fatigability)

muscle energy metabolism (=ATP production rate, activity of mitochondrial respiratory complexes, citrate synthase activity)

Cardiorespiratory fitness and anaerobic threshold (during incremental cycling test)

Secondary outcome

* Questionnaires on muscle complaints, fatigability and quality of life (short-form McGill pain questionnaire, and short-form Brief Fatigue Inventory, and short-form 36)

* Blood parameters

Study description

Background summary

Chronic myeloid leukemia (CML) is a disease with a good prognosis since the discovery of the targeted tyrosine kinase inhibitors (TKI) therapy last decade. However, musculoskeletal pain/myalgia is a frequently reported adverse drug reaction of TKIs (80% of patients reporting an adverse drug reaction, reports muscle complaints), leading to poor drug adherence. To data little research has been done on the pathogenesis and clinical management of musculoskeletal problems during TKI therapy. This is of utmost importance since: i) the onset of musculoskeletal problems contributes to the poor adherence to TKI therapy and ii) continuous, potentially lifelong treatment with TKIs is required for CML disease control. Therefore, this study will be performed to gain more

insight into the onset of TKI-induced muscle complaints, and whether they are associated with changes in muscle function.

Study objective

Primary Objective:
To investigate whether differences exist in muscle function, muscle energy metabolism and cardiorespiratory fitness in CML patients with muscle complaints, compared to CML patients without muscle complaints, and controls (non-CML patients).

Secondary Objective(s):
To investigate whether differences in muscle function, energy metabolism and cardiorespiratory fitness relate to pain intensity, fatigue and quality of life.

Study design

A cross-sectional, observational study with invasive measurements will allow comparison of muscle function, muscle energy metabolism and cardiorespiratory fitness between CML patients with muscle complaints, CML patients without muscle complaints and controls (non-CML patients).

Study burden and risks

During this study CML patients will not be exposed to a major risk, as standard care will not be withheld: patients will not be taken off their medication and will be carefully screened by a medical doctor.
Contra-indications for the maximal aerobic cycling test and muscle biopsy will be checked during the medical screening procedure and are listed as exclusion criteria for the study.
Venous blood withdrawal and collection of a muscle biopsy can induce a local hematoma (<5%). However, this is completely reversible within 2 weeks and will not induce permanent damage. Collection of a muscle biopsy will leave a small scar.
Taken together, the nature and extent of burden and risks associated with the different measurements are negligible.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein 10

Nijmegen 6500 HB
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein 10
Nijmegen 6500 HB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

age: >18 years old
CML patient using any TKI (group 1 and 2)
mentally able/ allowed to give informed consent

Exclusion criteria

known hereditary muscle defect
medication known to cause muscle pain (statins, antidepressiva, antipsychotica, thyroid hormones)
evident prolonged QTc interval (>500 msec)
contra-indication for maximal aerobic exercise test or muscle biopsy

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):	15-03-2017
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	09-02-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-05-2017
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
CCMO	NL59390.091.16

Study results

Date completed:	24-11-2017
Actual enrolment:	30