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Transfusion use in patients with rare blood cancer (myelodysplastic syndromes)

Submission date 13/01/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 24/01/2020	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 02/09/2021	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Myelodysplastic syndrome (MDS) is a type of blood cancer that limits the body's ability to produce blood cells. Patients with MDS receive an especially large number of blood transfusions. It is well known that a significant fraction of all manufactured blood units are transfused to patients with blood disorders, such as leukemia. Many patients with MDS get very large numbers of transfusions, resulting in very large costs. However, previous studies have not been able to estimate the total costs for transfusion therapy for this patient group, and has not been able to look in detail at these costs.
In the proposed project researchers will calcluate how much blood patients with MDS receive and what transfusion therapy for these patients would cost.

Who can participate?
All adult patients with a confirmed histopathological diagnosis of MDS in the time period from 2008-2017, living in Sweden.

What does the study involve?
Patient records will be analysed to estimate the costs related to blood transfusions.

What are the possible benefits and risks of participating?
None.

Where is the study run from?
Karolinska Institutet, Sweden

When is the study starting and how long is it expected to run for?
February 2020 to August 2020

Who is funding the study?
1. Celgene, USA
2. Vetenskapsrådet (Swedish Research Council, VR)

Who is the main contact?
Dr Gustaf Edgren
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Study website
http://www.scandat.se

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1

Study information

Scientific Title
Transfusion use in patients with myelodysplastic syndromes (MDS): a nationwide, retrospective cohort study

Acronym

SCANDAT

Study objectives
The overarching aim of the study is to perform a detailed characterization of blood transfusion use -- incorporating ensuing direct and indirect costs -- for patients with myelodysplastic syndromes (MDS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/05/2019 Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02, Uppsala, Sweden; +46 10-475 08 00; registrator@etikprovning.se), ref: 2018/167-31 and 2019-02636

Study design
Retrospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Myelodysplastic syndromes

Interventions
The study will include all adult patients with a confirmed histopathological diagnosis of MDS in the time period from 2010-2017, living in Sweden. In these patients, researchers will use nationwide registers to identify all blood transfusions. By incorporating known direct costs, and projected indirect costs, for transfusion therapy, researchers will estimate both blood use and the overall total costs for transfusion therapy in this patient group. Analyses will be conducted by first computing a cumulative number of transfusions per patient as a function of time since diagnosis and then the cumulative average number of transfusions for each patient by dividing this number with the corresponding number of patients who remain alive and under follow-up at the same time. Using this adjusted model, researchers can derive blood utilization estimates which incorporate both mortality, cure following aggressive treatment such as transplantation, as well as transition between risk groups. Estimates will thus be more specific for the subgroup at hand. Confidence intervals for averages can be constructed using boot strap methods. All analyses will be stratified by patient IPSSR risk group.

Intervention Type
Procedure/Surgery

Primary outcome measure
Total transfusion cost, incorporating both direct and indirect costs, related to blood transfusions measured using patient records

Secondary outcome measures
Measured using patient records:
1. Total direct cost for transfusion therapy
2. Total indirect for transfusion therapy
3. Total number of blood transfusions, overall, and divded by component type

Overall study start date
01/01/2019

Completion date
01/07/2020

Eligibility

Key inclusion criteria
Adult patients with a confirmed histopathological diagnosis of MDS in the time period from 2008-2017, living in Sweden

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
3,000

Total final enrolment
2858

Key exclusion criteria
Reseachers will restrict the analyses to patients with known WHO-subgroup and IPSS/IPSS-R risk group respectively

Date of first enrolment
01/01/2008

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Sweden

Study participating centre
Karolinska Institutet
Box 281
Stockholms
Sweden
17177

Sponsor information

Organisation
Karolinska Institute

Sponsor details
Department of Medicine Solna, Karolinska Institutet
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Sponsor type
University/education

Website
http://ki.se/en/startpage

ROR
https://ror.org/056d84691

Funder(s)

Funder type
Not defined

Funder Name

Celgene

Alternative Name(s)
Celgene Corporation

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Funder Name
Vetenskapsrådet

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Results and Publications

Publication and dissemination plan
Results will be published in an international peer reviewed journal.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to no IRB approval granted to share data.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Protocol file	version v4.0		05/02/2020	No	No
Results article		11/05/2021	02/09/2021	Yes	No