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Can we detect early chemotherapy related heart damage in patients with lymphoma using advanced echocardiography?

Submission date
29/08/2018

Recruitment status
No longer recruiting

Registration date
31/08/2018

Overall study status
Completed

Last Edited
07/07/2020

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Lymphoma is a type of cancer affecting the infection-fighting cells of the immune system called the lymphocytes (or white cells). There are different types of lymphoma depending on the type of cells affected. The two most common types include non-Hodgkin's and Hodgkin's lymphoma. In the UK, lymphoma is the fifth most common type of cancer. There are many different treatment options available for lymphoma; the most common treatment is chemotherapy. Chemotherapy uses anticancer (cytotoxic) drugs to destroy cancer cells by disrupting their growth. The most frequent cytotoxic drugs used are anthracyclines. These drugs have proven to be beneficial in the treatment of lymphoma and other types of cancer. However, despite their excellent anti-cancer properties, heart damage is considered to be one of the associated side effects of these agents. Once this occurs, heart damage can affect the length and quality of life of those patients affected. Therefore early detection of heart side effects is crucial.
Currently in the UK, detecting anthracycline-related heart damage relies on heart scans called echocardiography (or echo). However current echo measurements used to detect these changes are limited. These measurements can only find changes when significant damage has already occurred.
Therefore this study has been designed to explore better means of detecting early anthracycline-related heart damage using novel echo measurements. Furthermore we would like to evaluate which patient specific factors increase the risk of developing anthracycline-related heart damage.

Who can participate?
Patients with a new diagnosis of lymphoma who have received anthracycline-based chemotherapy between January 2015 to January 2018

What does the study involve?
Due to retrospective nature of the study no additional study procedures will be carried out. Patients will not be required to attend any additional hospital visits for the purpose of this study. Echocardiograms done as part of standard care (before chemotherapy, mid treatment and post chemotherapy) will be analysed using advanced echo measurements to explore whether

better methods of detecting early anthracycline induced cardiotoxicity exist. Furthermore patients' medical records will be reviewed to assess which factors increase the risk of developing anthracycline related heart damage.

What are the possible benefits and risks of participating?
The study is observational, exploratory and retrospective. No additional intervention or hospital visits are required for the purpose of this study and results obtained and published will not identify any individual participant. The novel echo measurements in question are not yet in routine clinical use. Thus, any findings are exploratory and as such will not impact patient management. This study will allow the exploration of novel echocardiographic measurements in detecting early anthracycline-related heart damage.

Where is the study run from?
James Cook University Hospital, Middlesbrough (UK)

When is the study starting and how long is it expected to run for?
July 2018 to July 2019

Who is funding the study?
South Tees Research and Development Research Fund (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1.0

Study information

Scientific Title
Detection of early anthracycline induced cardiotoxicity using speckle tracking echocardiography in patients with lymphoma: a retrospective cohort study

Study objectives
To check whether advanced strain measurements using speckle tracking echocardiography is able to detect subclinical cardiac dysfunction in patients with lymphoma treated with anthracyclines

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/10/2018, South East Scotland Research Ethics Committee 02 (Waverley Gate, 2 - 4 Waterloo Place, Edinburgh, EH1 3EG, UK; +44 (0)131 465 5674; Joyce.Clearie@nhslothian.scot.nhs.uk), REC ref: 18/SS/0139

Study design
Observational single-centre retrospective cohort study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Lymphoma

Interventions
This will be a single-centre, retrospective cohort study at the James Cook University Hospital in Middlesbrough. Patients diagnosed with lymphoma between January 2015 to January 2018 will be identified via the caring haematology team through a computerised search of the haematology database. As part of standard care, patients will have had an echocardiogram pre-chemotherapy, mid-treatment and post chemotherapy. The echocardiograms will be further analysed using advanced speckle tracking echocardiography in an offline workstation at The James Cook University Hospital echo core laboratory. This will allow us to explore whether any single or combined advanced echo measurements can detect early anthracycline induced cardiotoxicity in those patients who have developed a reduction in their heart function using conventional methods, to see whether this is evident at an earlier time point and whether the measures are reliable and reproducible. Furthermore patients' medical notes will be reviewed to obtain medical history and medication and to be able to link the information obtained with the echo measurements to assess which patient specific characteristics further increase the risk of anthracycline induced cardiotoxicity.

Intervention Type
Other

Primary outcome(s)
In addition to describing the medical characteristics of patients with lymphoma in the study, the cardiac function of patients will be measured. This will be assessed by echocardiogram, including:
1. Measurement of left ventricular ejection fraction (LVEF)
2. Measurement of all novel echocardiographic strain parameters on already performed echo scans done prior to chemotherapy, mid-treatment and post chemotherapy:
2.1. Left ventricular global longitudinal strain (GLS)
2.2. Left ventricular global radial strain (GRS)
2.3. Left ventricular global circumferential strain (GCS)
2.4. Torsion and twist
2.5. Right ventricular free wall strain
2.6. Left and right atrial strain
2.7. Strain rates

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
01/07/2019

Eligibility

Key inclusion criteria
1. New diagnosis of histopathologically-confirmed lymphoma between January 2015 and January 2018
2. Received anthracycline based chemotherapy for the treatment of their lymphoma

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
45

Key exclusion criteria
1. No adequate echocardiographic imaging on PACS database
2. Explicit dissent and unwillingness to participate in research detailed in the medical notes

Date of first enrolment

01/01/2015

Date of final enrolment
31/01/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The James Cook University Hospital
South Tees NHS Foundation Trust
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Sponsor information

Organisation
South Tees NHS Foundation Trust

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Not defined

Funder Name
Retrospective study so no need for funding for this study

Results and Publications

Individual participant data (IPD) sharing plan

There are no plans to disseminate any results that include identifiable personal data. Data will be fully anonymised prior to publication. Results will be presented in aggregated form in publications. In order to minimise exposure to patients' identifiable information we feel it is unnecessary to obtain patient phone number and address to disseminate the results. Specific consent is not being sought, and findings will not affect their clinical care.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	results abstract	01/01/2020	06/07/2020	No	No
HRA research summary			28/06/2023	No	No