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GA101 (obinutuzumab) monoclonal antibody as consolidation therapy In CLL

Submission date 08/01/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/01/2015	**Overall study status** Completed	
Last Edited 31/07/2017	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-whether-obinutuzumab-after-chemotherapy-for-cll-can-reduce-the-chances-of-the-leukaemia-coming-back-galactic

Contact information

Type(s)
Scientific

Contact name
Mr Jamie Oughton

Contact details
Clinical Trials Research Unit (CTRU)
Leeds Institute of Clinical Trials Research
University of Leeds
Leeds
United Kingdom
LS2 9JT

Additional identifiers

EudraCT/CTIS number
2014-000880-42

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17787

Study information

Scientific Title
GA101 (obinutuzumab) monocLonal Antibody as Consolidation Therapy In CLL: a randomised controlled trial

Acronym
GALACTIC

Study objectives
The trial will compare the use of obinutuzumab (GA101) in patients who have recently responded to treatment for chronic lymphocytic leukaemia (CLL) with the current standard practice, which is no treatment. The trial will evaluate whether obinutuzumab, if given after chemotherapy when there will be fewer CLL cells remaining, will keep patients disease free for longer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/YH/1199

Study design
Randomised; Interventional

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Cancer; Subtopic: Haematological Oncology; Disease: Leukaemia(Chronic Lymphocytic Leukaemia)

Interventions
Obinutuzumab, Intravenous infusion on days 1 & 2 then weekly (days 8, 15 and 22) and fortnightly (days 26, 50, 64, 78). Approx 3 months total.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Obinutuzumab

Primary outcome measure
Progression free survival (phase III); Timepoint(s): Disease progression or death

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/12/2014

Completion date
17/09/2018

Eligibility

Key inclusion criteria
1. At least 18 years old
2. Previous confirmation of B-CLL with a characteristic immunophenotype (for example, CD5+, CD19+, CD23+ lymphoproliferative disorder) on peripheral blood flow cytometry
3. Maximum of three prior therapies received for CLL treatment and between 3 and 24 months post therapy at registration
4. Response to most recent chemotherapy treatment for CLL with PR, CRi or CR
5. World Health Organisation (WHO) performance status (PS) of 0 or 1
6. Able to provide written informed consent
7. Peripheral B-Cell count <5x10^9 L
8. For randomisation, the first MRD positive peripheral blood sample (disease level found in peripheral blood is greater than 0.01%) must be between 3 and 12 months since completing most recent therapy for CLL
9. Absence of clinically or radiologically evident lymphadenopathy (largest lymph node 1.5 cm or less in minimum diameter)
10. Creatinine and bilirubin <2 times upper limit of normal unless secondary to direct infiltration of the liver by CLL or haemolysis
Target Gender: Male & Female

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 188; UK Sample Size: 188

Key exclusion criteria
1. Disease progression after response to latest therapy
2. Active infection
3. Past history of anaphylaxis following exposure to rat or mouse derived CDR-grafted humanised monoclonal antibodies
4. Previous treatment with obinutuzumab
5. CNS involvement with CLL
6. Mantle cell lymphoma
7. Moderate or severe cardiac disease that would preclude treatment with obinutuzumab
8. Other severe, concurrent diseases or mental disorders that could interfere with ability to participate
9. Known HIV positivity
10. Active secondary malignancy excluding basal cell carcinoma
11. Active haemolysis
12. Patients previously treated with allogeneic Stem Cell Transplant
13. Pregnancy, lactation or women of childbearing potential unwilling to use medically approved contraception whilst receiving treatment and for 12 months after treatment has finished
14. Men whose partners are capable of having children but who are not willing to use appropriate medically approved contraception whilst receiving treatment and for 12 months after treatment has finished, unless they are surgically sterile
15. Persisting severe pancytopenia (neutrophils <0.5 x 10^9/L or platelets <50 x 10^9/L) or trans fusion dependent anaemia
16. Positive serology for Hepatitis B (HB) defined as a positive test for HBsAg. In addition, if negative for HBsAg but HBcAb positive (regardless of HBsAb status), a HB DNA test will be performed and if positive the subject will be excluded.
17. Positive serology for Hepatitis C (HC) defined as a positive test for HCAb, in which case reflexively perform a HC RIBA immunoblot assay on the same sample to confirm the result.

Date of first enrolment
06/02/2015

Date of final enrolment
24/02/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Clinical Trials Research Unit (CTRU)
Leeds Institute of Clinical Trials Research
University of Leeds
Leeds
United Kingdom
LS2 9JT

Sponsor information

Organisation
University of Leeds

Sponsor details
Faculty of Medicine and Health
Academic Unit of Musculoskeletal and Rehabilitation Medicine
36 Clarendon Road
Leeds
England
United Kingdom
LS2 9NZ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	26/07/2017		Yes	No
HRA research summary			28/06/2023	No	No