

# GA101 (obinutuzumab) monoclonal antibody as consolidation therapy In CLL

<b>Submission date</b> 08/01/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 12/01/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 31/07/2017	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-whether-obinutuzumab-after-chemotherapy-for-ctl-can-reduce-the-chances-of-the-leukaemia-coming-back-galactic>

## Contact information

### Type(s)

Scientific

### Contact name

Mr Jamie Oughton

### Contact details

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Leeds  
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## 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  $<5 \times 10^9$  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  $<0.5 \times 10^9/L$  or platelets  $<50 \times 10^9/L$ ) or transfusion 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?
<a href="#">Protocol article</a>	protocol	26/07/2017		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No