ISRCTN68967559 https://doi.org/10.1186/ISRCTN68967559

Phase II randomised, double-blind, placebo controlled, multicentre study of orally administered ATL-104 (by swallowable mouthwash) to assess safety and tolerance and effect on oral mucositis in patients with haematological malignancies after treatment with chemotherapy associated with peripheral blood stem cell transplant (PBSCT)

Submission date 05/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/09/2005	**Overall study status** Completed	
Last Edited 20/01/2011	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00163280

Secondary identifying numbers
ATL-104/034/CL

Study information

Scientific Title

Study objectives
Is ATL-104 safe and well tolerated and does it show evidence of efficacy in mucositis in patients undergoing PBSCT?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Mucositis in the mouth and gastrointestinal tract

Interventions
ATL-104 (50 mg, 100 mg or 150 mg) or placebo, given as a swallowable mouth wash, as three single daily doses prior to commencement of PBSCT and three single daily doses following PBSCT.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
ALT-104

Primary outcome measure
1. Safety: adverse events
2. Efficacy: oral mucositis scale

Secondary outcome measures
1. Safety parameters including laboratory monitoring, vital signs, electrocardiogram (ECG)
2. Pharmacokinetics of ATL-104

Overall study start date
01/07/2004

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. Aged 18 - 65 years
2. With haematological malignancies
3. Undergoing chemotherapy in association with PBSCT

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Clinically significant conditions that would exclude the patient receiving chemotherapy in association with PBSCT
2. Visible oral disease
3. Significantly reduced platelet or neutrophil count

Date of first enrolment

01/07/2004

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Alizyme (UK)

Sponsor details
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Sponsor type
Industry

Website
http://www.alizyme.com

Funder(s)

Funder type
Industry

Funder Name
Alizyme (UK)

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?
Results article	results	01/04/2009		Yes	No