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		
Registration date	Overall study status	Statistical analysis plan		
16/09/2005	Completed	[X] Results		
Last Edited 20/01/2011	Condition category Digestive System	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Robert Marcus

Contact details

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Additional identifiers

ClinicalTrials.gov (NCT)

Protocol serial number

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

Study type(s)

Treatment

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(s)

- 1. Safety: adverse events
- 2. Efficacy: oral mucositis scale

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

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

Sponsor information

Organisation

Alizyme (UK)

Funder(s)

Funder type

Industry

Funder Name

Alizyme (UK)

Results and Publications

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