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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**ClinicalTrials.gov (NCT)**

NCT00163280

### 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

### Primary study design
Interventional

### Study design
Randomised controlled trial

### 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 |