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A preliminary, double centre, randomised controlled trial on patients with radiotherapy induced oral mucositis

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 17/05/2012	**Condition category** Cancer	

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

Secondary identifying numbers
N0203139308

Study information

Scientific Title

Study objectives
The use of Gelclair in the management of patients with radiotherapy induced mucositis, will significantly reduced levels of intro-oral pain and consequently improve the patients' ability to eat and drink

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Double centre randomised controlled trial

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Radiotherapy induced mucositis

Interventions
Randomised controlled trial. A sample of patients who are due to receive radiotherapy to the Head and Neck and who would normally be expected to develop oral mucositis will be approached for recruitment into the study. 20 Subjects from the Royal Devon & Exeter (RD&E) Healthcare Trust and South Devon Healthcare Trust, who fit the criteria for the study, will be selected and then randomly assigned to one of two treatment arms. The treatment groups will receive Gelclair plus standard therapy and the control groups will receive standard therapy alone. A baseline questionnaire will be completed before the patient starts taking their treatment regime and then subsequently re-completed at 1 hour, 3 hours and 24 hours. The independent variables to be measured will be A. Standard Therapy, B Gelclair. The dependent variables to be measured will be A. Patients pain levels at baseline, 1, 3 and 24 hours respectively, B. Patients ability to eat and drink at baseline, 1, 3, & 24 hours respectively.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
This study aims to evaluate short-term symptom control offered by Standard Therapy vs Gelclair, in patients suffering from radiotherapy-induced oral mucositis. Due to the escalating nature of this condition, the trial will be conducted over a period of 24 hours only.
Study endpoints: Comparing
1. Patients' inability to eat and drink
2. Pain levels
In control and treatment groups

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2004

Completion date
30/09/2004

Eligibility

Key inclusion criteria
A sample of patients who are due to receive radiotherapy to the Head and Neck and who would normally be expected to develop oral mucositis, will be approached for recruitment into the study. 20 subjects from the RD&E Healthcare Trust and South Devon Healthcare Trust, who fit the criteria for the study, will be selected and then randomly assigned to one of two treatment arms.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20 Subjects from the Royal Devon & Exeter (RD&E) Healthcare Trust and South Devon Healthcare Trust,

Key exclusion criteria
Those unable to give informed consent, patients who are known to be allergic to any of the constituents of Gelclair or standard therapy, those under the age of 18 years.

Date of first enrolment
01/03/2004

Date of final enrolment
30/09/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Devon & Exeter Hospital (Wonford)
Exeter
United Kingdom
EX2 5DW

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Devon and Exeter NHS Trust (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	01/04/2007		Yes	No