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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Miss Claire Hitchinson

Contact details

Royal Devon & Exeter Hospital (Wonford)
Barrack Road
Exeter
United Kingdom
EX2 5DW
claire.hitchinson@rdehc-tr.swest.nhs.uk

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