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Effect of a topical treatment on skin when having chemotherapy and radiotherapy to the head and neck

Submission date
30/04/2012

Recruitment status
No longer recruiting

Registration date
08/05/2012

Overall study status
Completed

Last Edited
12/02/2021

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Radiotherapy is a widely used treatment for various types of cancer. The aim of radiotherapy is to precisely target a tumour with x-rays whilst limiting the volume of normal tissue exposed to radiation. Normal skin tissue is sensitive to radiation. During a course of radiotherapy, temporary skin reactions are common. Some reactions are immediate, while others may be later (e.g., months after treatment). Radiation dermatitis occurs to some degree in most patients receiving radiotherapy, with or without chemotherapy. Radiation dermatitis can be painful and embarrassing, and has been associated with decreased quality of life. Severe radiodermatitis can cause treatment to be changed or delayed, which may reduce the effectiveness of the radiotherapy. Each treatment centre has its own ways to treat radiation dermatitis. However, apart from altering the radiotherapy treatment itself, no treatments have been shown to reduce the incidence of radiation dermatitis. There is therefore a need for studies to test the effectiveness of new treatments compared to standard skin-care treatment for radiation dermatitis. Water-Jel Technologies develop and manufacture products to treat patients who develop thermal burns. Audits showed that many hospitals were using Water-Jel's regular burn dressings on patients who had skin reactions following radiotherapy. As these products were not designed to treat this condition, Water-Jel undertook extensive research to develop a new compound to specifically treat these skin reactions. The aim of this study is to compare standard skin care with a new topical treatment (R1&R2) for the treatment of radiation dermatitis in patients undergoing radiation therapy for head and neck cancer.

Who can participate?
Patients aged 18 and over with head and neck cancer receiving platin-based radiochemotherapy.

What does the study involve?
Participants are randomly allocated to one of two groups. One group is treated with topical R1&R2 and the other group receives standard treatment. The number of patients with radiation dermatitis during the treatment and the 55-65 day follow-up period is recorded.

What are the possible benefits and risks of participating?
Treatment with R1&R2 may reduce the severity of radiation dermatitis. To date there have been no reports of side effects or any adverse reactions to the treatment.

Where is the study run from?
Radiotherapy departments in Czech Republic, Spain, Germany, Austria, and in the UK.

When is the study starting and how long is it expected to run for?
April 2011 to October 2012.

Who is funding the study?
Water-Jel Technologies (UK).

Who is the main contact?
Dr Karin Potthoff

Contact information

Type(s)
Scientific

Contact name
Dr Karin Potthoff

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evaluation of the effects of topical R1 and R2 for prophylaxis of acute radiation dermatitis in patients with head and neck cancer receiving platin-based radio-chemotherapy

Acronym
Cream-1

Study objectives
The trial is designed as a randomized trial with a 1:1 assignment to the two groups.

The primary objective is to show, that the rate of patients experiencing a radiodermatitis with a maximum grade of 3 or 4 (according to the NCI CTCAE classification, V. 4.03) during the treatment and the 55-65 day follow-up period is considerably and clinically relevantly decreased by the application of topical R1 and R2. Thus, the hypothesis formulation, as well as the test of the primary endpoint, is one-sided:

H0: radiodermatitis rate (R1 & R2) ≥ radiodermatitis rate (control)
H1: radiodermatitis rate (R1 & R2) < radiodermatitis rate (control)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical Faculty Heidelberg [Ethikkommission der Medizinischen Fakultät Heidelberg], 28/02/2011

Study design
National multicenter study

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 contact info@waterjel.net to request a patient information sheet

Health condition(s) or problem(s) studied
This is a national multicenter study to assess acute radiodermatitis in patients with non-metastatic squamous cell carcinoma of the head and neck (SCCHN) receiving platin-based radiochemotherapy

Interventions
Rate of radiodermatitis grade 3 and 4 in patients receiving topical R1&R2 will be compared to patients receiving standard treatment of the institution by Fishers exact text, with 95% confidence intervals provided for the odds ratio and the rate difference.

Analysis populations:
Intent-to-treat population: This population will include all patients who are eligible for the

suggested treatment protocol, regardless of whether they receive radiochemotherapy, R1 and R2 or other supportive care. This will be the primary population for evaluating the primary endpoint, all efficacy endpoints as well as patient characteristics.
Per-protocol population: A sensitivity analysis is performed in the subgroup of patients receiving the full course of radiochemotherapy administered according to the study plan (or with treatment stopped due to radiodermatitis)

Safety population: All patients having received at least one application of R1&R2 therapy are evaluable for device safety.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Improvement of rate of acute radiation induced dermatitis (radiodermatitis) grade 3/4 during platin-based radiochemotherapy. Severity graded by the National Cancer Institute, Common Terminology Criteria for Adverse Events [CTCAE] Version 4.03

Secondary outcome measures
1. Rate of radiodermatitis grade 1 and 2
2. Objective Response rate (ORR)
3. Locoregional control (LRC)
4. Progression free survival (PFS)
5. Overall survival (OS)
6. Safety profile of R1 and R2
7. Safety profile of applied radiation protocol
8. Quality of Life (QoL)

Overall study start date
01/04/2011

Completion date
01/10/2012

Eligibility

Key inclusion criteria
1. Histologically confirmed non-metastatic squamous-cell carcinoma of the oral cavity, oro- or hypopharynx and larynx (adjuvant or additive radiochemotherapy post surgery, i.e. R0-, R1- or Rx-resection) or primary definitive treatment concept in patients with LASCCHN UICC stadium III, IVA or IVB) or patients with nasopharyngeal carcinoma
2. Platin-based radiochemotherapy
3. ECOG Performance Status of 0-2
4. More than or equal to 18 years of age
5. Life expectancy of at least 6 months
6. Signed and dated informed consent before the start of specific protocol procedures
7. Women of childbearing potential must have had a negative serum or urine beta-HCG pregnancy test within 7 days prior to the first administration of study treatment or must have a

documented condition that prohibits pregnancy (e.g. post-menopausal; hysterectomy)
8. Patients enrolled in this trial must be willing to use effective birth control measures during the course of the trial and the subsequent 2 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
102

Key exclusion criteria
1. Distant metastases
2. Previous radiotherapy for carcinoma of the head and neck
3. Participation in other clinical trial within 30 days prior to start of study treatment
4. Concomitant treatment with epidermal growth factor (EGFR) targeted therapy.
5. Known hypersensitive reaction to any of the components of study treatments
6. Previous or concurrent cancer within 5 years prior to study entry that is distinct in primary site or histology except adequately treated basal cell carcinoma or pre-invasive cervical carcinoma.
7. Pregnant or breast-feeding patients
8. Substance abuse, medical, psychological or social conditions that may interfere with the patients participation in the study or evaluation of the study results as judged by the investigator

Notes:
The applied platin-based chemotherapy in combination with radiotherapy could be Cisplatin or Carboplatin or Cisplatin/5-Fluorouracil or Carboplatin/5-Fluorouracil.
The indication for radiochemotherapy could be an adjuvant or an additive or a primary definitive treatment concept. Furthermore, a patient previously treated with induction chemotherapy is allowed to participate in this trial.
Previous exposure to epidermal growth factor (EGFR) targeted therapy is allowed. Concomitant treatment with EGFR targeted therapy is an exclusion criterion.

Date of first enrolment
01/04/2011

Date of final enrolment
01/10/2012

Locations

Countries of recruitment
Germany

Study participating centre
Heidelberg University Hospital [Universitatskinikum Heidelberg]
Heidelberg
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69120

Sponsor information

Organisation
Water-Jel Technologies (UK)

Sponsor details
3&4 Mead Business Centre
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United Kingdom
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Sponsor type
Industry

Website
http://www.waterjel.net/

ROR
https://ror.org/01e98yd03

Funder(s)

Funder type
Industry

Funder Name
Water-Jel Technologies (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?
Other publications	case report	01/06/2013	12/02/2021	Yes	No