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Efficacy and safety of topical SR-T100® gel in the treatment of human cutaneous squamous cell carcinoma in situ (actinic keratosis and Bowen's disease)

Submission date 04/08/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 19/08/2009	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 19/08/2009	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

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
MCCD06003A

Study information

Scientific Title
An open phase II study to assess the efficacy and safety of topical SR-T100® gel in the treatment of human cutaneous squamous cell carcinoma in situ (actinic keratosis and Bowen's disease)

Study objectives
In our preliminary animal study to evaluate the efficacy and toxicity of topical SR-T100® gel, using an approved protocol of ultraviolet B (UVB)-induced hairless mouse (HRS) cutaneous cell carcinoma, 35 of 40 squamous cell carcinomas (SCCs) disappeared within 10 weeks of treatment (once-daily). Besides the high complete response rate (87.5%) as compared with the conventional therapy, the most significant result was that no undesirable side effects were associated with the use of SR-T100® gel.

We hypothesise that SR-T100® gel can be a potential alternative treatment for cutaneous squamous cell carcinoma in situ (actinic keratosis and Bowen's disease).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Experiment and Ethics Committee of National Cheng Kung University Hospital approved on the 20th July 2007 (ref: HR-94-72).

Study design
Single centre phase II open-label study

Primary study design
Interventional

Secondary study design
Non 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
Human cutaneous squamous cell carcinoma in situ (actinic keratosis and Bowens disease)

Interventions

Only one lesion will be selected for treatment and assessment in each patient. SR-T100® gel will be applied once daily on the targeted lesion and covered with an occlusive dressing. Patients will be instructed to apply the study gel to the entire area of target lesion including its peripheral normal skin approximately 1 cm around the tumour. Treatment will be continued until tumour is clinically cleared or until 16 weeks of treatment completed. The 16 week treatment is chosen on the basis of maximum duration treatment of topical drug on actinic keratosis and Bowen's disease previously reported.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
SR-T100® gel

Primary outcome measure
To assess the response rate of SR-T100® in patients with cutaneous squamous cell carcinoma in situ (actinic keratosis and Bowen's disease), defined as the proportion of patients whose lesion size (length x width x height) is reduced greater than 75%. Measured until tumour is clinically cleared or until 16 weeks of treatment completed.

Secondary outcome measures
1. Complete clearance rate, defined as the proportion of patients with no clinically visible actinic keratosis and Bowen's disease lesions in the treatment area
2. Partial clearance rate, defined as the proportion of patients with at least a 75% reduction of actinic keratosis and Bowen's disease lesion size (length x width x height) in the treatment area
3. Histological response rate: proportion of patients with biopsy proven clearance of cutaneous squamous cell carcinoma in situ (actinic keratosis and Bowen's disease)
4. The safety profile of SR-T100® gel

Measured until tumour is clinically cleared or until 16 weeks of treatment completed.

Overall study start date
01/12/2007

Completion date
30/06/2009

Eligibility

Key inclusion criteria
Patients must meet ALL of the inclusion criteria for the entry of this study:
1. Male or female; aged greater than or equal to 20 years old
2. Patients must have histologically confirmed squamous cell carcinoma in situ (actinic keratosis or Bowen's Disease) for the target lesion
3. Patients must have a measureable lesion 5 mm or larger for actinic keratosis of 10 mm or larger for Bowen's disease
4. Patients must have a performance of less than or equal to 2 (Eastern Cooperative Oncology

Group [ECOG])
5. Patients who have signed an approved written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
15 patients for actinic keratosis and 15 patients for Bowen's disease

Key exclusion criteria
Patients will be excluded from this study for ANY of the following reasons:
1. Patients with histologic subtypes other than squamous cell carcinoma in situ (actinic keratosis or Bowen's disease)
2. Patients with tumour extending into the oral cavity, nostrils, eyelids, urethra, anus, vagina or rectum
3. Patients who have grossly suspicious or inflamed nodes on physical examination
4. Patients with grossly infected tumours
5. Patients with recurrent invasive squamous cell carcinoma
6. Patients with a history of other invasive malignancies, if there is any evidence of the other malignancy being present within the past 5 years. Patients are also excluded if their previous cancer treatment contraindicates this protocol therapy.
7. Use of any investigational drug in the 30 days before screening
8. Pregnant or lactating women or women of childbearing potential using inadequate contraceptive methods

Date of first enrolment
01/12/2007

Date of final enrolment
30/06/2009

Locations

Countries of recruitment
Taiwan

Study participating centre
No. 138, Sheng-Li Road
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Sponsor information

Organisation
G&E Herbal Biotech (Taiwan)

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
G&E Herbal Biotech (Taiwan) (ref: RDP009)

Funder Name
Department of Industrial Technology, Ministry of Economic Affairs (Taiwan) (ref: 97-EC-17-A-20-I1-0003)

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