ISRCTN84460768 https://doi.org/10.1186/ISRCTN84460768

Effect of additional single or repeated dosage of Kappaproct® to corticosteroid treated patients with brain oedema caused by brain tumour

Submission date 22/10/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 02/12/2009	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 02/12/2009	**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

Protocol serial number
InDex-CSBTE-01-09

Study information

Scientific Title

Effect of additional single or repeated dosage of Kappaproct® to corticosteroid treated patients with brain oedema caused by brain tumour: a multicentre open one-arm non-randomised trial

Acronym
Kappaproct® study

Study objectives
To evaluate the effect of an additional single dose of Kappaproct® to corticosteroid treated patients with brain oedema caused by brain tumour, measured as reduction of the volume of the oedema by magnetic resonance imaging (MRI).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethical Committee in Umeå approved on the 1st April 2009 (ref: 09-054M)

Study design
Open one armed non-randomised multicentre trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Brain oedema due to brain tumour

Interventions
A single dose of 30 mg Kappaproct® (DIMS0150) given as a rectal enema. The patients are followed for 20 days after treatment.

Intervention Type
Drug

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
Kappaproct®

Primary outcome(s)
Efficacy assessment: measurement of the volume of the brain oedema with MRI, measured at 10 days after treatment.

Key secondary outcome(s))

Assessed at 10 and 20 days after treatment:
1. Efficacy assessment: Clinical assessment of symptoms of brain edema, dose of steroids, in an explorative manner immune response in blood will be followed.
2. Safety and tolerability after one dose of Kappaproct® treatment

In an explorative manner, immune response in blood will be studied. This samples are collected before treatment and at 24 hours and 10 days after treatment.

Completion date
31/10/2011

Eligibility

Key inclusion criteria
1. Adult men and women (greater than 18 year) with malignant brain oedema confirmed by MRI /computed tomography (CT), caused by malignant glioma, menigioma or metastatic disease (histological and/or cytological verified)
2. World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) performance 0 - 3
3. Betapred® (betamethasone) dose 8 mg x 2 for more than 24 hours
4. Clinical need for increase of corticosteroid dosage
5. Possibility to perform repeated MRI examinations

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. History and precence of a clinical significant cardiovascular, hepatic, haematological, endocrine, neurological and psychiatric disease or immune compromised state as judged by the investigator
2. Chemotherapy that has been administrated within 4 weeks prior to inclusion
3. Positive urine pregnancy test in women at enrolment
4. Intake of drug under investigation

Date of first enrolment
01/11/2009

Date of final enrolment

31/10/2011

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Oncology
Umeå
Sweden
SE-90185

Sponsor information

Organisation
InDex Pharmaceutials AB (Sweden)

ROR
https://ror.org/05225cn18

Funder(s)

Funder type
Industry

Funder Name
InDex Pharmaceutials AB (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration