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**<br>22/10/2009 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>02/12/2009 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>02/12/2009 | **Condition category**<br>Cancer | [_] Individual participant data<br>[_] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Thomas Asklund

**Contact details**
Department of Oncology
Norrlands University Hospital
Umeå
Sweden
SE-90185

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

### 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
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 measure
Efficacy assessment: measurement of the volume of the brain oedema with MRI, measured at 10 days after treatment.

### Secondary outcome measures
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.

### Overall study start date
01/11/2009

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants

Total = 30 patients. An evaluation will be done after 10 patients.

### 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)

### Sponsor details
Scheeles väg 2
Stockholm
Sweden
SE-171 77
svante.rasmuson@indexpharmab.com

### Sponsor type
Industry

### Website
http://www.indexpharmab.com/

**ROR**
https://ror.org/05225cn18

# Funder(s)

**Funder type**
Industry

**Funder Name**
InDex Pharmaceutials AB (Sweden)

# 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