

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 02/12/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 02/12/2009	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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, meningioma 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 Pharmaceuticals AB (Sweden)

ROR

<https://ror.org/05225cn18>

Funder(s)

Funder type

Industry

Funder Name

InDex Pharmaceuticals AB (Sweden)

Results and Publications

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?
	Participant information sheet				

