Det Videnskabsetisk Komitésystem

(S3)

Informed consent for participating in a clinical trial

Research project title:

A combined treatment with GM-CSF, fosfomycin and metronidazole for pouchitis in ulcerative colitis patients after restorative ileal pouch anal anastomosis surgery

A clinical safety and proof-of-concept study .

En kombinationbehandling med GM-CSF, fosfomycin og metronidazol mod pouchitis ved colitisulcerosa patienter, efter ileal-pouch analanstomose. Et klinisk sikkerheds- og pilotstudie

Phase 1 study

Statement from the trial participant:

I have received written and verbal information and I know and understand enough about the reason, methods, benefits and disadvantages of this trial to agree to participate.

I know that it is voluntary to participate in this trial, and that I at any point in time can retract my consent without losing my current and future rights to treatment.

I give consent to participate in this clinical trial, and that biological material is taken for storage in a research biobank. I have received a copy of this informed consent form as well as a copy of written information about this project for my own use.

Trial participant's name: _____

Date:_____ Signature_____

Would you like to be informed about the trial's results as well as whether this has any consequences for you?

Yes_____(put an x) No_____(put an x)

Statement from the one that gives trial information:

I declare that the trial participant has received verbal and written information about the trial.

In my belief there has been given sufficient information so that the participant can decide whether ornot to participate in the clinical trial.

Name of the person giving information: Viviane Lin, MD

Date:_____ Signature:_____

EudraCT nr: 2020-000609-10
Participant information version 4 – English Phase 1

Informed Consent version 1

(S3)

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Phase 2 study

Statement from the trial participant:

I have received written and verbal information and I know and understand enough about the reason, methods, benefits and disadvantages of this trial to agree to participate.

I know that it is voluntary to participate in this trial, and that I at any point in time can retract my consent without losing my current and future rights to treatment.

I give consent to participate in this clinical trial, and that biological material is taken for storage in a research biobank. I have received a copy of this informed consent form as well as a copy of written information about this project for my own use.

Trial participant's name: _____

Date:_____Signature_____

Would you like to be informed about the trial's results as well as whether this has any consequences for you?

Yes_____(put an x) No_____(put an x)

Statement from the one that gives trial information:

I declare that the trial participant has received verbal and written information about the trial.

In my belief there has been given sufficient information so that the participant can decide whether or not to participate in the clinical trial.

Name of the person giving information: Viviane Lin, MD

Date:_____Signature:_____