



# Update on the MesaCapp Study

Christina Therkildsen and Lars Joachim Lindberg

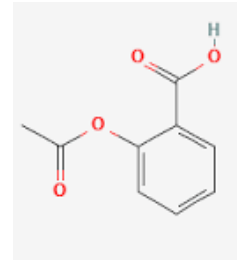




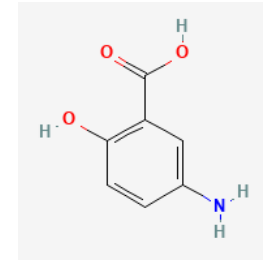
## Mesalamine (5-ASA)

- Mesalamine is used to treat mild to moderate ulcerative colitis.
- Anti-inflammatory
- In 2007, Mesalamine was associated with colorectal cancer reduction in patients with ulcerative colitis

Aspirin



Mesalamine



## Rationale

- Aspirin and Mesalamine share biologic similarities
  - Same biologic effect on the COX2 inhibition and inflammation
- Mesalamine has some advances
  - Additional effects on apoptosis, inflammation, and the generation of ROS and frameshift mutations in microsatellites
  - Local effect -> Less side effects than Aspirin
- Side effects from Aspirin
  - Need alternatives

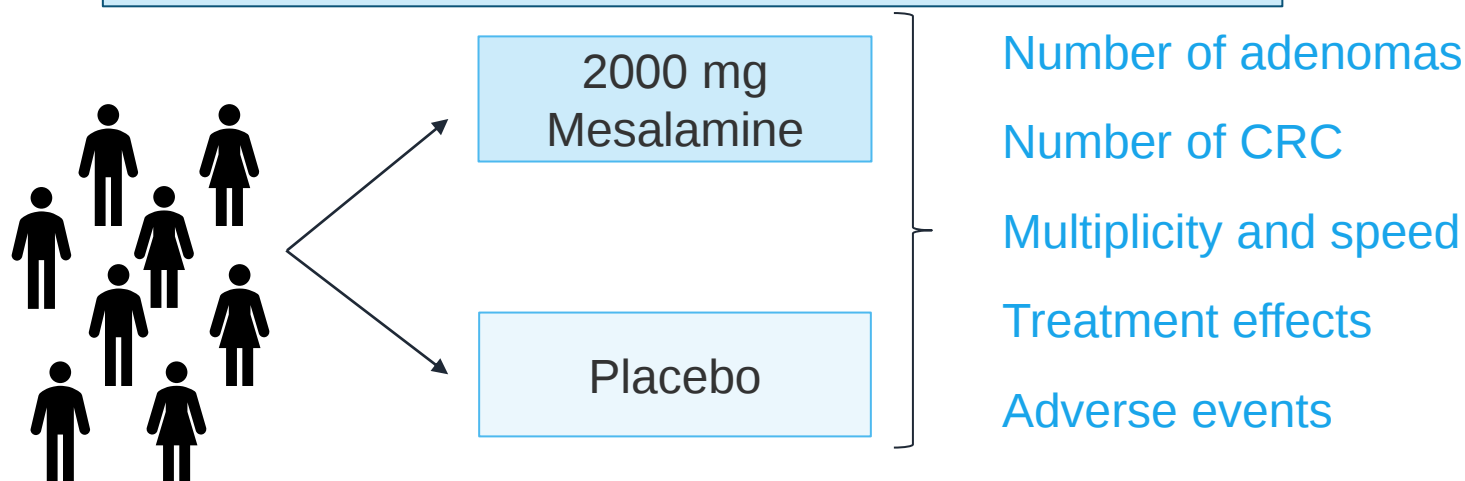


## MesaCAPP – like CAPP2

- 2022 – 2042, 260 participants, 6 countries, incl. Denmark

**Expected to find a 50% reduction in  
the development of adenoma/CRC**

Follow-up:



<https://clinicaltrials.gov/ct2/show/NCT04920149>



## Principal investigator and funding

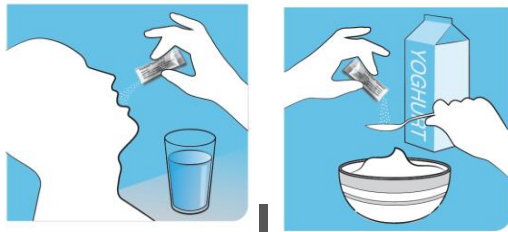
- Ann-Sofie Backman, PhD and MD
- Karolinska Institute, Stockholm, Sweden
- Funding from the Swedish Research Council
- Sponsored by Ferring, donate Mesalamin and placebo
- Co-authorships given for at least 5 participants
- Approximately 9000 DKK per patient included and 3000 per screening failure





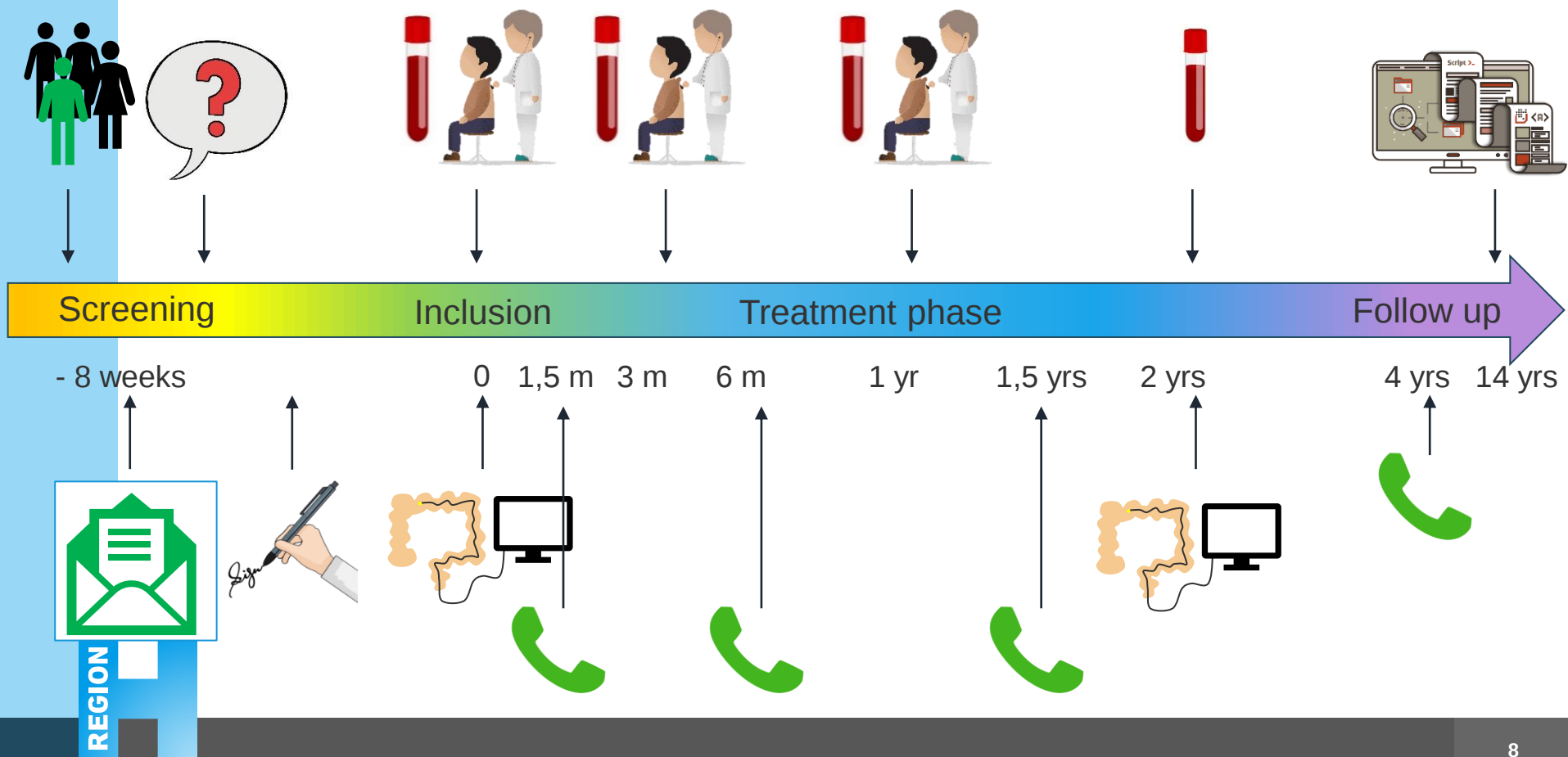
## Study design

- Daily treatment with Mesalamine/placebo for 2 years
- Routine colonoscopy at entry and after 2 years
- Blood sample, physical examination, organ control (before inclusion, at 3 months, 1 year and 2 year)
- Follow up telephone interview at 4 years
- Follow up with no patient contact for 14 years



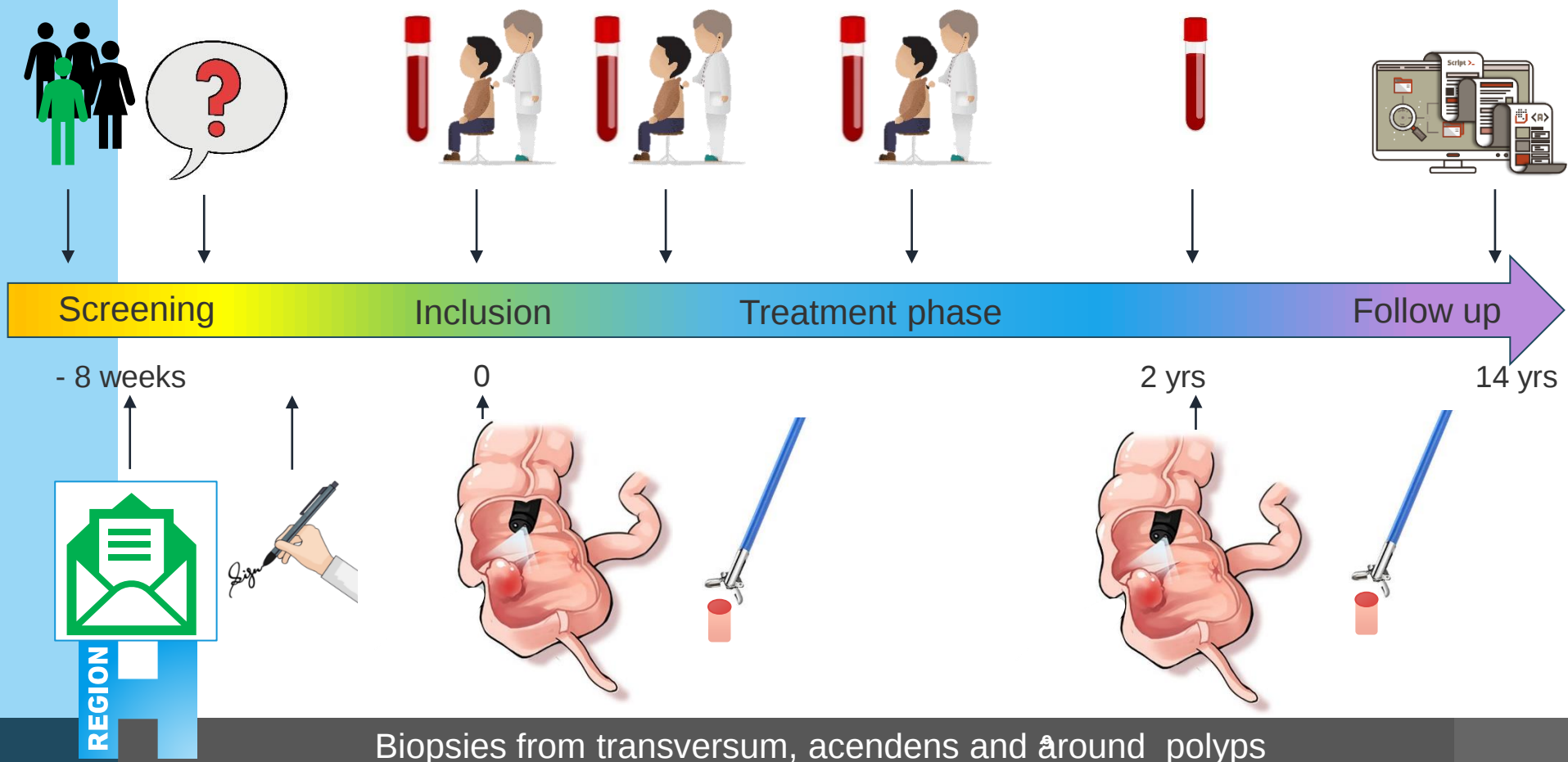


## Flow chart





## Flow chart





## Paperwork done!

- Scientific Medical Ethical Committee in Denmark (approved in August 2022)
- Danish Medicines Agency (approved in June 2022)
- Danish Data protection Agency (Site-specific and Coordinator contracts approved in September 2022)
- Registration at the EudraCT (EU clinical Trial database)
- Contract with the local GCP unit (monitorization)
- All necessary documents translated to Danish
  - Patient diary
  - Invitations and project information
  - Flowchart etc.



## Patient inclusion proces

- Patients can be identified through the HNPCC register or at Clinical Departments

We have invited 10 individuals

physical examination

- Patients attend colonoscopy as planned (but with additional images and biopsies)



## What is required for you to participate

- New sites added to the Protocol for the Ethical Committee
- New sites added to the Protocol at the Danish Medicines Agency and EudraCT
- Danish Data protection Agency (Site-specific contracts needs to be approved by local lawyers at your hospital)
- A monitor plan is required with your local GCP unit
- Local agreements with your Pathology Department, Clinical Biochemical Department and Endoscopic Department



## What is required for you to participate

- You will be trained in the protocol and how to react on adverse events (24-hour phone service for 6 years/pts)
- You will be trained in the eCRF
- You need GCP training
- The HNPCC Register will provide you with the patient diaries
- The medicine will be delivered directly at your hospital
- You will report the data directly to the main database and ship the samples and temporarily store samples in your local freezer



## Join us

By writing an email to

[Christina.Therkildsen@regionh.dk](mailto:Christina.Therkildsen@regionh.dk) or

[Tine.vester.christensen@regionh.dk](mailto:Tine.vester.christensen@regionh.dk)

