

Aspirin as secondary prevention in colorectal cancer liver metastasis (ASAC trial): Study protocol for a multicentre randomized placebo-controlled trial

Sheraz Yaqub (✉ sheraz.yaqub@ous-hf.no)

Oslo University Hospital <https://orcid.org/0000-0002-5696-2319>

Bjørn Atle Bjørnbeth

Oslo University Hospital

Jon-Helge Angelsen

Haukeland University Hospital: Haukeland Universitetssjukehus

Claus Wilki Fristrup

Odense University Hospital: Odense Universitetshospital

Jon Erik Grønbech

St Olavs Hospital

Oskar Hemmingsson

Umea University Faculty of Medicine: Umea Universitet Medicinska fakulteten

Bengt Isaksson

Uppsala University Hospital: Akademiska sjukhuset

Ingebjørg Soterud Juel

St Olavs Hospital University Hospital in Trondheim: St Olavs Hospital Universitetssykehuset i Trondheim

Peter Nørgaard Larsen

Copenhagen University Hospital: Rigshospitalet

Gert Lindell

Skåne University Hospital Lund: Skanes universitetssjukhus Lund

Frank Viborg Mortensen

Aarhus University Hospital Skejby: Aarhus Universitetshospital

Kim Erlend Mortensen

University Hospital of Northern Norway

Magnus Rizell

University of Gothenburg: Goteborgs Universitet

Per Sandström

County Council Ostergotland: Region Ostergotland

Oddvar Mathias Sandvik

Stavanger Universitetssjukehus: Helse Stavanger HF

Ernesto Sparrelid

Karolinska University Hospital: Karolinska Universitetssjukhuset

Helena Taflin

Sahlgrenska University Hospital: Sahlgrenska universitetssjukhuset

Kjetil Taskén

Oslo Universitetssykehus Institutt for kreftforskning

Study protocol

Keywords: Colorectal cancer, liver metastases, aspirin, acetylsalicylic acid, secondary prevention

Posted Date: April 8th, 2021

DOI: <https://doi.org/10.21203/rs.3.rs-401696/v1>

License:   This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

Abstract

Background: Colorectal cancer is one of the most common cancers in the western world with increasing incidence. Approximately 50% of the patients develop liver metastases. Resection of liver metastases is treatment of choice although almost half of the resected patients get recurrence in the liver.

Methods: The ASAC trial is a Scandinavian, multi-centre, double-blinded, randomized, placebo-controlled study to determine whether adjuvant treatment with low-dose Aspirin (acetylsalicylic acid (ASA)) can improve disease-free survival in patients treated for colorectal cancer liver metastases (CRCLM). Up to 800 patients operated for CRCLM will be randomized to Arm#1 ASA 160 mg once daily or Arm#2 Placebo, for a period of 3 years or until disease recurrence. The patients will be recruited at all major hepatobiliary surgical units in Norway, Sweden and Denmark and have follow-up according to standard of care and the National Guidelines.

Discussion: The ASAC trial will be the first clinical interventional trial to assess the potential beneficial role of ASA in recurrence of CRCLM and survival. ASA is an inexpensive, well tolerated, and easily accessible drug that will be highly potential as adjuvant drug in secondary prevention of CRCLM if the study shows a beneficial effect. We will also determine the effect of ASA as adjuvant treatment on Health-Related Quality of Life and the cost-effectiveness.

Trial registration: ClinicalTrials.gov Identifier: NCT03326791. Registered 31 October 2017, <https://clinicaltrials.gov/ct2/show/NCT03326791?term=asac&draw=2&rank=1>

Full Text

This preprint is available for [download as a PDF](#).

Figures

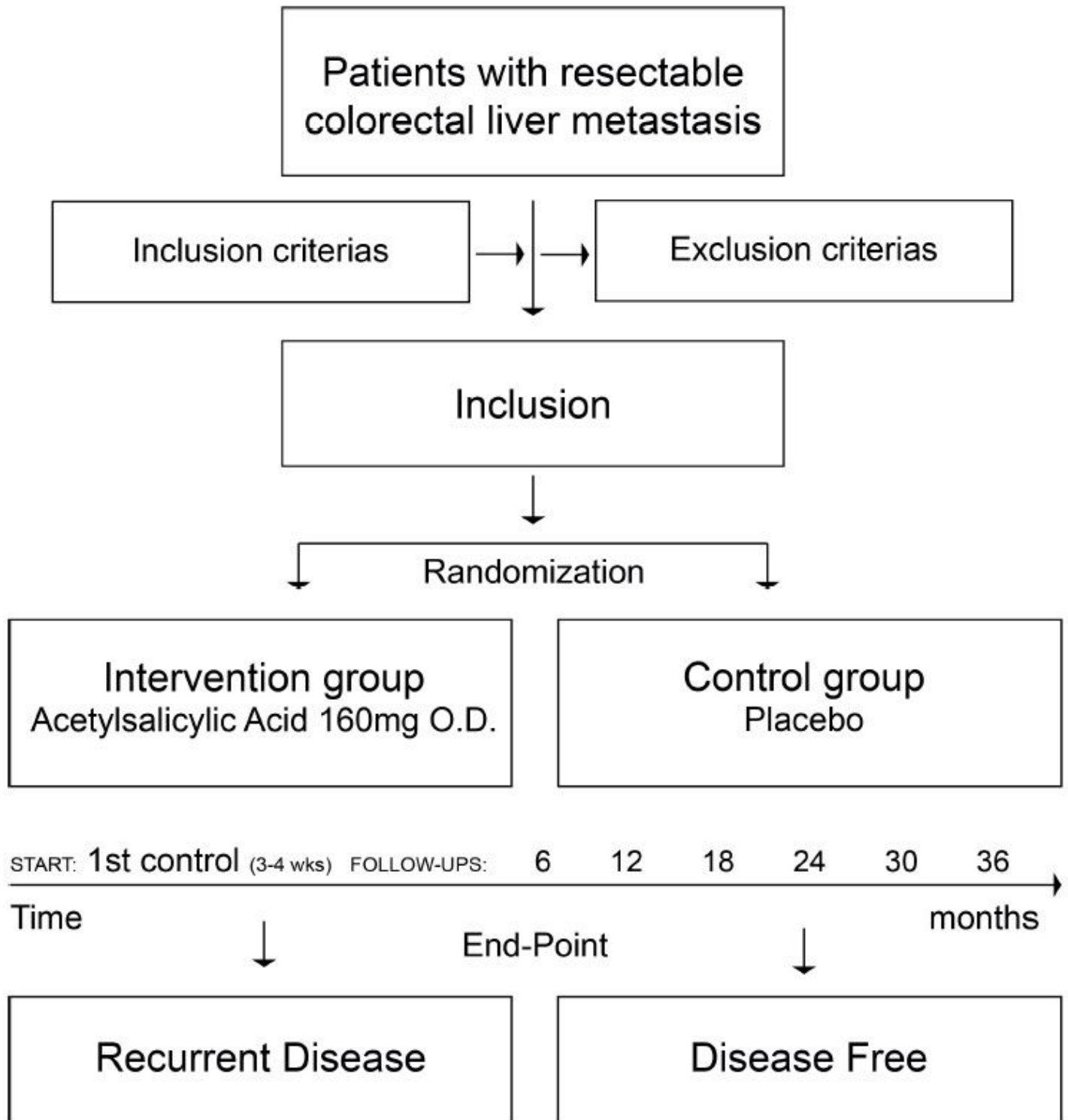


Figure 1

Flowchart of the ASAC trial.

Visits	1	2 <i>Drug start*</i>	3	4	5	6	7	8 <i>Drug stop</i>	Withdrawal visit
Timeline (months) (+/- 14 days), Norway, Sweden and Denmark	0	0	6	12	18	24	30	36	
Informed consent	X								
Subject screening	X								
Demographics	X								
Medical history	X								
Surgery	X								
Concomitant medicines	X	X	X	X	X	X	X	X	X
Vital signs	X								
Physical exam	X								
Tumour markers (CEA)	X		X	X	X	X	X	X	X
Blood samples	X								X
Study drug dispensing		X		X		X			
Study drug collecting				X		X		X	X
CT-scan (chest & abdomen) or MRI of the liver	X (pre-op.)		X	X	X	X	X	X	X
Adverse events			X	X	X	X	X	X	X
Questionnaires (SF-36 and EQ-5D)	X		X	X	X	X	X	X	X
Recurrence assessment			X	X	X	X	X	X	X
Survival assessment			X	X	X	X	X	X	X

Figure 2

Schematic overview of timeline for patients included in the ASAC trial.