Aspirin summaries: 2023 clinical trials update

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The future for aspirin – 2023 clinical trials update

This summary celebrates the continuing research interest in aspirin and gives us a taste of potential developments in the role aspirin may play in future healthcare.

A search of recruiting and not yet recruiting trials on the U.S National Library of Medicine Clinical Trials.gov platform gives 159 trials for aspirin. This is very active for a drug that is over 125 years old and to put it into context with other medicines the same search was conducted for clinical trials of some commonly used medications with the following results:

- Betablockers = 49 trials
- Statins = 95 trials
- Paracetamol = 76 trials
- Prednisolone = 76 trials
- Amoxicillin = 40 trails
- Ramipril = 7 trials
- Metformin = 209 trials

Aspirin trials were being organised across USA [32], Canada [13], Brazil [4], Europe, [44], Africa [3], Asia [46] and Australia [1].

The conditions being studied for aspirin were also diverse and included:

- Coronary Heart Disease (including coronary artery disease, peripheral artery disease and cardiovascular disease in general) = 33 trials
- Pregnancy, pre-eclampsia, postpartum = 29 trials
- Cancer prevention and management= 26 trials
- Neurology including stroke prevention and management = 18 trials
- Surgery = 11 trials
- Aspirin tolerability, side effects, aspirin exacerbated respiratory disease (AERD) = 9
- Diabetes = 5 trials
- Aspirin pharmacology- timings body weight etc. =5
- Pain = 4 trials
- Psychiatry = 4
- Covid-19 = 3 trials
- Blood disorders= 3
- Renal (chronic kidney disease) = 2 trials
- Tuberculosis = 2 trials
- Respiratory/COPD = 2
- NAFLD= 1
- Sepsis = 1

Inflammatory processes in many conditions are an attractive target for aspirin therapy. Perhaps it may be true that 'an aspirin a day keeps the doctor away'.

The following is a summary of the design of some the trials first listed between June 2022 and July 2023 giving a taster of what the future may hold for aspirin if they reach their primary end points.

References

1. https://www.clinicaltrials.gov/

Pregnancy/postpartum

ClinicalTrials.gov Identifier: NCT05653973

Title: Prenatal Aspirin and Postpartum Vascular function

The aim of this study is to gain greater understanding as to how low dose aspirin reduces vascular dysfunction in postpartum women experiencing preeclampsia.

Recruitment status: Recruiting

First posted: 07/12/22

Lasted updated post: 16/12/22

Location: US

Phase: Early phase 1

Estimated enrolment: 60

Intervention arm: Experimental assessment of microvascular function, single group assignment

Design: Interventional, basic science

Estimated primary competition date: 31/03/2025

Estimated study competition date: 30/04/2025

ClinicalTrials.gov Identifier: NCT05557877

Title: Low Dose Aspirin for the Prevention of Postpartum Related Breast Cancer

Can low-dose aspirin affect markers of inflammation in blood and tissue and thereby prevent postpartum related breast cancer?

Recruitment status: Recruiting

First posted: 08/09/2022

Lasted updated post: 19/05/2023

Location: US

Phase: Phase 2

Estimated enrolment: 100

Intervention arm: Low dose aspirin

Design: Interventional single group assignment

Estimated primary competition date: 30/01/2026

Estimated study competition date: 30/01/2027

Primary outcome measure: Change in pregnancy related breast cancer

ClinicalTrials.gov Identifier: NCT05709483

Title: Predictors of Aspirin Failure in Preeclampsia Prevention

Despite currently being the most beneficial prophylactic approach for preeclampsia, aspirin failure to reduce hypertensive disorders of pregnancy is not uncommon. The aim of this study is to understand the role of a genetic variant in the PAR4 receptor expressed on platelets and explore whether it is associated with increased platelet function and possible aspirin failure.

Recruitment status: Recruiting

First posted: 02/02/2023

Lasted updated post: 07/04/2023

Location: US

Phase: Early phase 1

Estimated enrolment: 130

Intervention arm: Thromboxane A2 levels measured at baseline and 1 hour after administration of 81 mg of aspirin

Design: Nonrandomised, parallel assignment, basic science

Estimated primary competition date: 01/11/2024

Estimated study competition date: 01/11/2024

Thrombocytopenia

ClinicalTrials.gov Identifier: NCT04912505

Title: ASPirin in Immune thRombocytopenia Patients with Cardiovascular disease

This study aims to assess the pharmacodynamics of once daily aspirin in people with thrombocytopenia.

Recruitment status: Recruiting

First posted: 03/06/2021

Lasted updated post: 10/032023

Location: France

Sponsors and collaborators: University Hospital, Toulouse

Phase: 2

Estimated enrolment: 10

Intervention arm: Aspirin

Design: Interventional single group assignment

Estimated primary competition date: 01/06/2023

Estimated study competition date: 01/09/2023

Primary outcome measure: platelet production of thromboxane B2 24 hours after a 75 mg aspirin intake

Chronic Obstructive Pulmonary Disease (COPD)

ClinicalTrials.gov Identifier: NCT05265299

Title: Trial to determine effective aspirin dose in COPD

COPD treatments currently focus on inhaler therapies for the lungs and do not target the impact of COPD in other body systems. Recent evidence suggests activated platelets, which are involved in inflammatory processes may make respiratory symptoms worse independent of CVD. It is interesting that patients with COPD taking aspirin have been shown to have improved respiratory symptoms, fewer COPD flares and lower mortality. The investigators intend to explore in a larger clinical trial whether aspirin use can improve respiratory symptoms independent of CVD but this initial study aims to find the best dose of aspirin for blocking platelet activation in this population and to find out if blood or urine tests can help us understand the response to therapy.

Recruitment status: Recruiting

First posted: March 3, 2022

Lasted updated post: 17/05/2023

Location: USA

Sponsor: John Hopkins University, National Heart, Lung, and Blood Institute (NHLBI)

Phase: 3

Estimated enrolment: 48 participants

Intervention arm: Aspirin 81 mg once daily, aspirin 162 mg once daily or aspirin 325 mg once daily

No intervention arm: 0

Design: Interventional, randomised sequential assignment with 6-sequence, 3-period, 3- treatment sequential crossover trial

Estimated primary competition date: December 2026

Estimated study competition date: December 2026

Primary outcome measure: Change in urinary 11-dehydro-thromboxane B2 level – a urinary metabolite of thromboxane A2

Secondary outcome measures: Change in proportion of platelets displaying CD62P, CD63, CD154 and PAC1 at 2, 6 and 10 weeks after stimulation with U46619, a thromboxane A2 agonist.

Cancer

ClinicalTrials.gov Identifier: NCT05865548

Title: Addition of Aspirin to Standard of Care in Oral Cancer

Is the impact of aspirin on cancer survival and prevention of recurrence linked to specific genes?

Recruitment status: Recruiting

First posted: 19/05/2023

Lasted updated post: 24/05/2023

Location: India

Sponsor: Banaras Hindu University

Estimated enrolment: 60

Intervention arm: Aspirin 150 mg daily plus standard care

No intervention arm: standard care

Design: Randomised parallel assignment

Estimated primary competition date: 30/09/2024

Estimated study competition date: 30/09/2024

Primary outcome measure: Number of patients with treatment related adverse events

Secondary outcome measure: Disease free survival, overall survival

Cardiovascular disease

ClinicalTrials.gov Identifier: NCT05347069

Title: Efficacy and Safety of Aspirin in Patients with Chronic Coronary Syndromes Without Revascularization.

Recruitment status: Recruiting

First posted: 26/04/2022

Lasted updated post: 17/08/2022

Location: Japan

Sponsor/Collaborator: Takeshi Morimoto

Phase: 4

Estimated enrolment: 2890 participants

Intervention arm: Aspirin 100 mg daily

No intervention arm: No aspirin

Design: Interventional, randomised, parallel assignment, open label

Estimated primary competition date: March 2030

Estimated study competition date: December 2030

Primary outcome measure: Composite cardiovascular events

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Psychiatry

ClinicalTrials.gov Identifier: NCT05615948

Title: Oral Aspirin + Ketamine as Adjunct to Oral Antidepressant Therapy for Depression

The aim of this study is to assess the effect of aspirin and ketamine as a therapy for people with treatment resistant depression.

Recruitment status: Recruiting

First posted: 14/11/2022

Lasted updated post: 05/07/2023

Location: USA

Sponsor: Maimonides Medical Center

Phase: 4

Estimated enrolment: 20

Intervention arm: Aspirin 486 mg and 80 mg ketamine

Design: Interventional, open label, single group assignment

Estimated primary competition date: 31/10/2023

Estimated study competition date: 31/10/2023

Primary outcome measure: Change in depressive symptoms on the Montgomery-Asberg Depression Rating Scale (MADRAS)

Preventing blood clots after joint replacement surgery

ClinicalTrials.gov Identifier: NCT04295486

Title: Optimal Dosing for Low-Dose Aspirin Chemoprophylaxis for VTE Following Total Joint Arthroplasty

The aim of this study is to find out if aspirin 81 mg once daily is as effective as 81 mg twice daily for preventing VTE after total joint replacement surgery.

Recruitment status: Recruiting

First posted: 04/03/2020

Lasted updated post: 02/03/2023

Location: USA

Sponsor: University of Miami

Phase: 2

Estimated enrolment: 5478

Intervention arm: 81 mg aspirin non-enteric coated tablet once daily from the night before surgery until 28 days post-surgery

No intervention arm/comparator arm: 81 mg non-enteric coated aspirin tablet from the night before surgery and then morning and night until 28 days post-surgery

Design: Interventional, randomised, parallel assignment open label

Estimated primary competition date: May 1, 2024

Estimated study competition date: May 1, 2024

Primary outcome measure: incidence of symptomatic thromboembolic events (PE and VTE) over 90 days.

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