ISRCTN11629849 https://doi.org/10.1186/ISRCTN11629849

Broccoli in osteoarthritis

Submission date	Recruitment status	[X] Prospectively registered
11/01/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/02/2019	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
05/05/2021	Musculoskeletal Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study is to find out if eating broccoli will improve pain and physical function in osteoarthritis. A naturally occurring compound sulforaphane (SFN), found in broccoli, has been shown to protect articular cartilage in our laboratory studies of osteoarthritis. We also know that by eating broccoli, SFN gets into our joint tissues. The study will compare broccoli soup (rich in SFN) with a soup that does not contain broccoli (control), but looks and tastes the same.

Who can participate?
Patients aged over 50 who have osteoarthritis (OA) and pain in at least one knee, who like broccoli

What does the study involve?
Participants are randomly allocated to either the broccoli or the control soup and eat this on 4 days per week for 3 months. Pain and physical function are measured at the start of the study, at 6 weeks and at 12 weeks. Blood and urine samples are also collected.

What are the possible benefits and risks of participating?
Given that this is a pilot trial, the researchers cannot be sure that there will be any medical benefits to taking part in this study and they do not anticipate any risks.

Where is the study run from?
This study is run by the University of East Anglia through two sites. The two trial sites are Norfolk and Norwich University Hospital (Norwich) and Chapel Allerton Hospital (Leeds) (UK)

When is the study starting and how long is it expected to run for?
April 2018 to September 2021 (updated 05/05/2021, previously: June 2020)

Who is funding the study?
Versus Arthritis (formerly Arthritis Research UK) and Action Arthritis

Who is the main contact?
1. Dr Rose Davidson

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2. Prof Alex MacGregor
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Study website
https://www.brio.uea.ac.uk/

Contact information

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT03878368

Secondary identifying numbers
BRIO Research Protocol V4.0 (01/08/2019)

Study information

Scientific Title
A dietary intervention trial to examine the effect of broccoli bioactives (specifically sulforaphane) on osteoarthritis (OA)

Acronym
BRIO

Study objectives
To determine whether dietary sulforaphane (SFN), naturally available from eating broccoli, improves pain in people with knee OA.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/01/2019, East of England - Cambridge East Research Ethics Committee, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, Tel: +44 (0)207 104 8101 or +44 (0)207 104 8095, Email: NRESCommittee.EastofEngland-CambridgeEast@nhs.net, ref: 19/EE0007

Study design
Pilot-scale clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Osteoarthritis

Interventions
Eligible, consented participants will be randomised on a 1:1 basis to one of two trial arms using a web-based randomisation process. The randomisation scheme will be generated by the Norwich Clinical Trials Unit data manager. Allocation will be stratified by centre (NNUH/CAH), gender (male/female) and age (<=60 / >60) using permuted block randomisation with randomly varying block sizes of 2 and 4.

The trial will compare broccoli soup (rich in SFN) with a soup which does not contain broccoli (control), but looks and tastes the same. Sixty-four patients with moderate osteoarthritis will

either have the broccoli or the control soup, chosen at random. They will eat the soup once a day for 4 days a week for 3 months. Pain and physical function will be measured at the start of the trial, at 6 weeks and at 12 weeks, and blood and urine samples are collected to measure SFN levels.

Intervention Type
Other

Primary outcome measure
Pain measured using the WOMAC (Western Ontario and McMaster Universities Arthritis Index) pain subscale, at baseline, 6 weeks, and 12 weeks

Secondary outcome measures
1. Pain and function in the knee measured using an 11-point NRS (Numerical Rating Scale) at baseline, 6 weeks, and 12 weeks
for:
1.1. Average overall knee pain severity in the index knee over the past 1 week
1.2. Worst knee pain severity in the index knee over the past 1 week
1.3. Global disease activity over the past 1 week
1.4. Satisfaction with index knee function over the past 1 week
1.5. Average pain in other joints over the past 1 week
2. Pain measured in other joints (joint manikin) at baseline, 6 weeks, and 12 weeks
3. Pain measured using Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP), at baseline, 6 weeks, and 12 weeks
4. Use of rescue analgesics/NSAIDs at baseline, 6 weeks, and 12 weeks

Overall study start date
02/04/2018

Completion date
01/09/2021

Eligibility

Key inclusion criteria
1. Current knee pain, defined as pain in either knee, in the (one) month before Visit 1, for which the patient gives a severity score of at least 4 on a 0-10 numeric rating scale (NRS).
2. The target knee should fulfil the criteria of the American College of Rheumatology (ACR) for knee osteoarthritis defined as knee pain for most days of the prior month and at least one of the following three factors: age over 50 years; morning stiffness of less than 30 minutes; knee crepitus on motion.
3. Kellgren Lawrence grade 2-3
4. Stable analgesic usage (if using) for 4 weeks prior to trial entry and throughout the trial duration
5. Able to adhere to the study visit schedule and other protocol requirements (willing to consume soup intervention).
6. Willing to provide 24 hour urine collection samples (x3)
7. Capable of giving informed consent and the consent must be obtained prior to any screening procedures

Participant type(s)

Other

Age group
Adult

Sex
Both

Target number of participants
64

Key exclusion criteria
1. The presence of any inflammatory arthritis (e.g. gout, reactive arthritis, rheumatoid arthritis, psoriatic arthritis, seronegative spondylarthropathy) or fibromyalgia or metabolic bone disease
2. Any clinically significant uncontrolled concurrent illness, which, in the opinion of the Investigator, would impair ability to give informed consent or take part in or complete this clinical study
3. Known or suspected intolerance or hypersensitivity to the investigational product (broccoli) or standardised meal (see section 9.2), closely related compounds, or any of the stated ingredients
4. Use of an investigational product within 30 days prior to 'run in' period or active enrolment in another drug or vaccine clinical study
5. Significant knee injury or any knee surgery within the 6 months preceding enrolment in the study
6. A history of partial or complete joint replacement surgery in the signal knee at any time, listed for knee surgery, or anticipating knee surgery during the study period
7. Poor tolerability of venepuncture or lack of adequate venous access for required blood sampling during the study period
8. Nutritional deficiency
9. Use of anticoagulant medication (see notes for inclusion exclusion criteria)
10. Use of intra-articular hyaluronic acid in the signal knee within the 3 months preceding enrolment in the study
11. Use of intra-articular, intra-muscular or oral corticosteroids in the 2 months preceding enrolment
12. Commencement of non-pharmacological interventions within two months preceding enrolment
13. Persons less than 50 years
14. Pregnant/lactating women

Removed 11/10/2019:
15. Smokers or those ceasing <3 months ago

Date of first enrolment
01/05/2019

Date of final enrolment
31/05/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Norfolk and Norwich University Hospital NHS Foundation Trust
Colney Lane
Norwich
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Study participating centre
Chapel Allerton Hospital
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Sponsor type
University/education

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results of the study will be presented at relevant clinical meetings and published in an appropriate peer reviewed journal. Participants will be offered the opportunity to be informed of the study results.

Intention to publish date
01/06/2022

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date