ISRCTN55839425 https://doi.org/10.1186/ISRCTN55839425

Joint and muscle aches, pains and stiffness in women with primary breast cancer

Submission date	Recruitment status	[_] Prospectively registered
28/09/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/10/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/10/2022	Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-joint-muscle-aches-pain-stiffness-women-breast-cancer-jacs

Contact information

Type(s)
Scientific

Contact name
Dr Deborah Fenlon

Contact details
University Road
Southampton
United Kingdom
SO17 1BJ
-
dfenlon@soton.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7170

Study information

Scientific Title
A longitudinal cohort study of joint and muscle aches, pains and stiffness in women with primary breast cancer

Acronym
JACS

Study objectives
1. To establish the natural history of joint and muscle aches, pains and stiffness (JaMAPS) over time in women being treated for early breast cancer (BC)
2. To investigate whether and how the prevalence and natural history of JaMAPS differs in women receiving adjuvant therapy for invasive early BC from that in women following treatment for ductal carcinoma in situ (DCIS)
3. To explore the impact of JaMAPS on quality of life (QoL) in women with invasive early BC
4. To explore their impact on functional ability
5. To undertake an exploratory analysis of how the natural history of JaMAPS differs between adjuvant treatment groups

Study findings will be used to educate health professionals about the natural history and impact of these under-researched and under-treated symptoms, better equipping them to support patients and enabling them to provide more accurate information to patients to inform treatment decisions. Findings will inform future research into both the causes of JaMAPS in BC and into effective interventions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved on 04/08/2009, ref: 09/H0501/44

Study design
Observational multicentre non-randomised longitudinal cohort study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Interventions will be determined by findings.

Follow up length: 3 months
Study entry: other

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Descriptive statistics will be used to describe the prevalence at Times 1 - 5 of joint stiffness

Secondary outcome measures
1. The statistical significance (if any) of differences in pain prevalence, severity and interference
2. Descriptive statistics will be used to describe the QoL and functional status of women at each time
3. Descriptive statistics will be used to compare joint pain, pain severity and interference
4. Exploratory analysis, again using descriptive statistics and the mixed method approach to modelling

Overall study start date
04/01/2010

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Diagnosis of BC (invasive or DCIS)
2. Aged at least 18 years old
3. No evidence of metastatic disease
4. Able to complete written records in English
5. Female

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned sample size: 500; UK sample size: 500

Total final enrolment
543

Key exclusion criteria
Men will be excluded from this study because their numbers are likely to be extremely low: effects of gender on joint pain can explored in a future multi-centred study.

Date of first enrolment
27/01/2010

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Road
Southampton
United Kingdom
SO17 1BJ

Sponsor information

Organisation
Southampton University Hospitals NHS Trust (UK)

Sponsor details
Cancer Care Directorate
B Level, Mailpoint WRE
Royal South Hants Hospital
Graham Road
Southampton

England
United Kingdom
SO14 0YG

Sponsor type
Hospital/treatment centre

Website
http://www.suht.nhs.uk/home.aspx

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Charity

Funder Name
Breast Cancer Campaign (UK) (ref: 2008MayPR49)

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
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/06/2014		Yes	No
Plain English results			25/10/2022	No	Yes