

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

Submission date 28/09/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/10/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 25/10/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

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

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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 be 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

United Kingdom

England

Study participating centre

University Road

Southampton

United Kingdom

SO17 1BJ

Sponsor information

Organisation

Southampton University Hospitals NHS Trust (UK)

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

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