Patient identification number _____

Patient initials _____

Barts Health NHS Trust

Barts and The London School of Medicine and Dentistry

CASE REPORT FORM

A multicentre double-blind randomised controlled trial to assess the clinical- and cost-effectiveness of facet-joint injections in selected patients with non-specific low back pain: a feasibility study.

Short title: Facet-joint feasibility study

Sponsor: Barts Health NHS Trust

Representative of the Sponsor:

Dr Sally Burtles

Director of Research Services

JRMO

QM Innovation Building

5 Walden Street

London

E1 2EF

Phone: 020 7882 7265

Email: sponsorsrep@bartshealth.nhs.uk

Chief investigator: Dr Vivek Mehta

Site principal investigator:

Co-investigators:

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Patient eligibility – inclusion criteria

Inclusion criteria		
	Yes	No
1. Patient aged 18 to 70 years attending pain clinics identified during routine clinical assessment of non-specific low back pain		
2. Low back pain of greater than three months' duration		
3. Average pain intensity score of 4/10 or more in the seven days preceding recruitment despite NICE recommended treatment		
4. Dominantly paraspinal (not midline) tenderness at two bilateral lumbar levels		
5. At least two components of NICE-recommended best non-invasive care completed, including education and one of a physical exercise programme, acupuncture, and manual therapy		
6. Patient is suitable for the facet- joint feasibility study		

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Patient eligibility – exclusion criteria

Exclusion criteria		
	Yes	No
1. Patient refusal to consent		
2. More than four painful lumbar facet-joints		
3. Patient has not completed at least two components of NICE-recommended best non-invasive care, including education and one of a physical exercise programme, acupuncture, and manual therapy		
4. 'Red flag' signs including thoracic pain, fever, unexplained weight loss, bladder or bowel dysfunction, progressive neurological deficit, and saddle anaesthesia		
5. Hypersensitivity to study medications		
6. Dominantly midline tenderness over the lumbar spine, any other dominant pain or radicular pain.		
7. Any major systemic disease or mental health illness that may affect the patient's pain, disability and/or their ability to exercise and rehabilitate, as judged by the Principal Investigators		
8. Any active neoplastic disease, including primary or secondary neoplasm		
9. Pregnant or breastfeeding		
10. Previous lumbar facet-joint injections, spinal surgery or any major trauma or infection to lumbar spine.		
11. Patient with morbid obesity (body mass index of 35 or greater)		
12. Participation in another clinical trial of a investigational medicinal product or disease related intervention in the past thirty days		
13. Patient unable to commit to the six-month study duration		
14. Patient involved in legal actions or employment or benefit tribunals related to their low back pain		
15. Patient with a history of substance abuse		

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Consent

Date of patient consent _____

Version of consent form used _____

Baseline pain score (NRS) up 7 days preceding recruitment ☐ date taken:

I confirm that this patient is eligible to enter the study _____

(signature of medical doctor on delegation log)

Patient visit schedule

		Date of visit(s)
Visit 1	Screening and informed consent Outcome questionnaires at baseline	
Visit 2	Diagnostic test (medial branch nerve blocks)	
Visit 3	Study procedure (facet-joint injections or sham procedure)	
	Combined physical and psychological programme	Date of first session: Date of last session: Number of sessions attended:
Visit 4	Outcome questionnaires at 6 weeks	
Visit 5	Outcome questionnaires at 3 months	
Visit 6	Outcome questionnaires at 6 months	

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Patient history

To be completed by research assistant

General health

How long has the patient been aware of his/her non-specific low back pain? _____ Years _____ Months

In general, would the patient describe his/her health as: (tick box)

- Excellent ☐
- Very good ☐
- Good ☐
- Fair ☐
- Poor ☐

Occupation information

What is the patient's current work status? (tick box)

- Full time ☐
- Part time ☐
- Volunteer ☐
- Modified duties ☐
- Disabled ☐
- Not working ☐
- Homemaker ☐
- Retired ☐
- Not applicable ☐

Type of work or occupation: _____

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Patient history

To be completed by research assistant

Did the patient's illness cause him/her to stop working?

- Yes ☐
- No ☐
- Not applicable ☐

Other (give reason):

_____

If the patient continued working, how many work days in the past 3 months, prior to the procedure, did he/she miss due to pain?

_____ days

What was the patient's level of activity prior to the procedure?

- Hard manual work ☐
- Lifting ☐
- Walking ☐
- Sedentary ☐

Social history

Smoking

- Current smoker ☐

  _____ cigarettes/day
- Ex-smoker ☐

  _____ date stopped
- Never smoked ☐

Alcohol

_____ Units consumed per week

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Patient history

To be completed by research assistant

Exercise per week: (tick box)	>5 days	☐
	3-5 day	☐
	1-2 days	☐
	Less than 1 day	☐

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Visit 1

Baseline

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Patient questionnaire

To be completed by research assistant

Treatments/hospitalisations/medications

Has the patient seen a healthcare professional within the past 4 weeks due to pain?

_____ Emergency department visits

_____ Length of stay in hospital

_____ GP appointments

_____ pain clinic

Other (give details):

_____

Current analgesics (name of medication, dosage and frequency)

Other medications (name of medication, dosage and frequency)

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Patient's expectation of benefit

How much improvement in pain does the patient expect from the procedure? (circle one)

1	2	3	4	5	6

Expect no improvement — Expect total improvement

Outcome questionnaires

Has the questionnaire pack (set 1) been completed?

Yes ☐

No ☐

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Visit 2

Diagnostic test

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Diagnostic test (medial branch nerve blocks)

To be completed by PI

Study centre _____

Date of procedure _____

Time of procedure _____

Operator _____

Procedure details Number of injections _____

IMP injected 1% lidocaine 0.5% per site

Levels injected

Post injection evaluation 1 (20 to 40 minutes after injection)

To be completed by PI

Time of evaluation _____

Minutes after injection _____

Please rate the patient's current level of pain on a numerical rating scale (NRS) of 0-10. (0 is no pain and 10 is worst pain):

Patient's current pain score = ☐

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Post injection evaluation 2 (180 to 240 minutes after injection)

To be completed by PI

Time of evaluation _____

Minutes after injection _____

Please rate the patient's current level of pain on a numerical rating scale (NRS) of 0-10. (0 is no pain and 10 is worst pain):

Patient's current pain score = ☐

Investigator decision: **positive test is a 50% or greater pain relief lasting more than 30 minutes** (circle one)

☐ Positive (for randomisation) **Date of randomisation** _____

☐ Negative (end of study)

Visit 3- Study procedures form the 'blinded CRF'

This section is to be completed by the PI and kept separately in a locked filing cabinet until unblinding

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Blinded CRF

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Chief investigator: **Dr Vivek Mehta**

Site principal investigator:

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Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Blinded CRF

Visit 3

Study procedure

Study procedure (facet-joint injections or sham procedure)

To be completed by PI

Study centre _____

Date of procedure _____

Time of procedure _____

Operator _____

Procedure details

Number of injections _____

Levels injected

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Combined physical and psychological programme

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Combined physical and psychological programme

Study centre _____

	Date attended	Outcomes delivered Y/N
Session 1	_____	Y/N
Session 2	_____	Y/N
Session 3	_____	Y/N
Session 4	_____	Y/N
Session 5	_____	Y/N
Session 6	_____	

If all outcomes not delivered please provide further details:

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Outcomes

6 Weeks Post Intervention

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Patient questionnaire

To be completed by research assistant

Treatments/hospitalisations/medications

Has the patient seen a healthcare professional within the past 4 weeks due to pain?

_____ Emergency department visits

_____ Length of stay in hospital

_____ GP appointments

_____ pain clinic

Other (give details):

_____

Current analgesics (name of medication, dosage and frequency)

Other medications (name of medication, dosage and frequency)

Patient's expectation of benefit

Investigator's initials _____

Date _____

Visit 4 – Outcome measures at 6 weeks

Patient identification number _____

Patient initials _____

How satisfied is the patient with the treatment received? (circle one)

0	1	2	3	4	5	6	7	8	9	10

Extremely dissatisfied Extremely satisfied

Outcome questionnaires

Has the questionnaire pack (set 2) been completed? Yes ☐

No ☐

Adverse events

Have there been any adverse events since the intervention? Yes ☐

No ☐

If yes, please complete the adverse event log at the end of the CRF

Changes to medications

Have there been any changes in medication since the intervention? Yes ☐

No ☐

If yes, please complete in box below:

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Outcomes

3 Months Post Intervention

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Patient questionnaire

To be completed by research assistant

Treatments/hospitalisations/medications

Has the patient seen a healthcare professional within the past 4 weeks due to pain?

_____ Emergency department visits

_____ Length of stay in hospital

_____ GP appointments

_____ pain clinic

Other (give details):

_____

Current analgesics (name of medication, dosage and frequency)

Other medications (name of medication, dosage and frequency)

Patient's expectation of benefit

Investigator's initials _____

Date _____

Visit 5 – Outcome measures at 3 months

Patient identification number _____

Patient initials _____

How satisfied is the patient with the treatment received? (circle one)

0	1	2	3	4	5	6	7	8	9	10

Extremely dissatisfied Extremely satisfied

Outcome questionnaires

Has the questionnaire pack (set 3) been completed? Yes ☐

No ☐

Adverse events

Have there been any adverse events since the last visit? Yes ☐

No ☐

If yes, please complete the adverse event log at the end of the CRF

Changes to medications

Have there been any changes in medication since the last visit? Yes ☐

No ☐

If yes, please complete in box below:

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Outcomes

6 Months Post Intervention

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Patient questionnaire

To be completed by research assistant

Treatments/hospitalisations/medications

Has the patient seen a healthcare professional within the past 4 weeks due to pain?

_____ Emergency department visits

_____ Length of stay in hospital

_____ GP appointments

_____ pain clinic

Other (give details):

_____

Current analgesics (name of medication, dosage and frequency)

Other medications (name of medication, dosage and frequency)

Patient's expectation of benefit

Investigator's initials _____

Date _____

Visit 6 – Outcome measures after 6 months

Patient identification number _____

Patient initials _____

How satisfied is the patient with the treatment received? (circle one)

0	1	2	3	4	5	6	7	8	9	10

Extremely dissatisfied Extremely satisfied

Outcome questionnaires

Has the questionnaire pack (set 4) been completed? Yes ☐

No ☐

Adverse events

Have there been any adverse events since the last visit? Yes ☐

No ☐

If yes, please complete the adverse event log at the end of the CRF

Changes to medications

Have there been any changes in medication since the last visit? Yes ☐

No ☐

If yes, please complete in box below:

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

End of study

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

End of study

To be completed by research assistant

Date of final study contact with patient _____

Reason (circle one)

- ☐ Completed study
- ☐ Withdrawn from study
- ☐ Other

Reason for withdrawal from study (circle one)

- ☐ Drop out
- ☐ Protocol non-compliance
- ☐ Adverse event (please complete AE form at the end of the CRF)
- ☐ Other

If other, provide further details:

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Adverse events

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Adverse events 1

Date adverse event occurred _____

Date investigator become aware of the event _____

Location of adverse event

_____

Event details:

Is the adverse event related to the procedure? (circle one only)

- ☐ Unrelated
- ☐ Unlikely
- ☐ Possible
- ☐ Probably
- ☐ Related

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Was the adverse event a serious adverse event (SAE)?

- ☐ Yes
- ☐ No (move on to action plan)

Serious criteria (circle all that apply)

- ☐ The AE led or could have led to a congenital anomaly/birth defect
- ☐ The AE led or could have led to death
- ☐ Resulted in medical or surgical intervention to prevent permanent impairment to a body structure
- ☐ Life-threatening illness or injury
- ☐ Resulted in permanent impairment of a body structure or body function
- ☐ Required inpatient hospitalisation
- ☐ Other

Action plan

- ☐ No action required
- ☐ Amend consent form
- ☐ Amend protocol
- ☐ Inform current subjects
- ☐ Terminate or suspend protocol
- ☐ Other

Has the Sponsor been informed?

- ☐ Yes
- ☐ No

If other, provide further details:

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Adverse events 2

Date adverse event occurred _____

Date investigator become aware of the event _____

Location of adverse event

_____

Event details:

Is the adverse event related to the procedure? (circle one only)

- ☐ Unrelated
- ☐ Unlikely
- ☐ Possible
- ☐ Probably
- ☐ Related

Investigator's initials _____

Date _____

Patient identification number _____

Patient initials _____

Was the adverse event a serious adverse event (SAE)?

- ☐ Yes
- ☐ No (move on to action plan)

Serious criteria (circle all that apply)

- ☐ The AE led or could have led to a congenital anomaly/birth defect
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Action plan

- ☐ No action required
- ☐ Amend consent form
- ☐ Amend protocol
- ☐ Inform current subjects
- ☐ Terminate or suspend protocol
- ☐ Other

Has the Sponsor been informed?

- ☐ Yes
- ☐ No

If other, provide further details:

Investigator's initials _____

Date _____

End of study

Patient identification number _____

Patient initials _____

Investigator's initials _____

Date _____