University Hospitals of Leicester NHS Trust

DIDACT

Insert hospital logo

Participant Information Sheet

DIDACT: A study comparing treatments for a break to the end of the collarbone

Your hospital is working with other hospitals on a study to compare two commonly used treatments in the NHS for the type of break to the end of the collarbone that you have had.

Both treatments are commonly used by NHS doctors and they know both treatments work well. This study aims to find out which treatment is best for patients.

Can you help?

- We are looking for 214 patients to take part in this study. Will you be one of them?
- You are free to decide whether to take part. You can stop taking part at any time.
- If you choose not to take part, you will still receive the best care this hospital can provide.
- Please read this information sheet carefully, before you decide whether to take part. It is important that you understand the study and what it means to take part.
- If you have any questions or concerns, please contact us using the details provided.

Summary of the DIDACT study

- We are comparing two treatments that NHS doctors use for this type of break to the end of the collarbone.
- Each patient who takes part will either start with a sling then consider surgery or have surgery from the start.
- Both treatments work, but we do not know which is best for patients. The aim of the study is to find this out.
- We will ask you to complete questionnaires at 6 weeks and at 3, 6 and 12 months to find out how you are doing. We will send you a gift voucher each time you do this.
- You will receive the same standard of care whether or not you take part in the study.
- Scan the QR code to watch an animation or use this link

https://youtu.be/H_2WgI7_jkw

Contents

DIDACT has been funded by the NIHR HTA. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health in Social Care.
DIDACT Participant Information Sheet _V3.0_2025.07.04 IRAS ID: 321203

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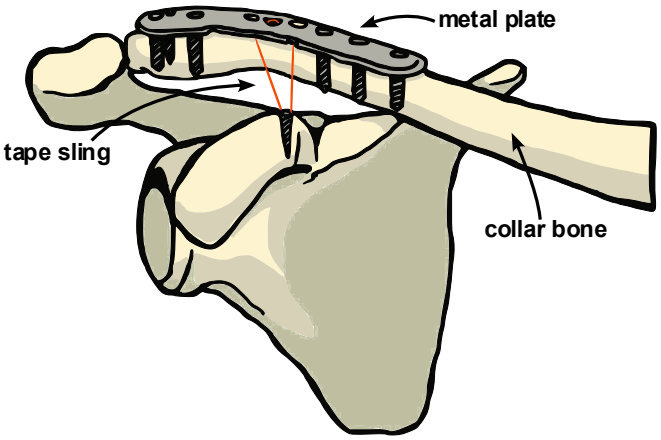
1 What is the aim of the study?

When the outer end of the collarbone (clavicle) has broken, parts of the bone may separate and not line up. This can rupture the ligaments connecting the collarbone to the shoulder blade. Doctors commonly treat this type of injury that you have had with:

- A sling, to help support the shoulder while the bone heals naturally; or
- Surgery that uses metal work to try and realign the separated bone while they knit together naturally.

Both treatments help to reduce pain, swelling and the bones to knit together. However, it is not known which treatment is best for patients. The aim of the study is to find this out.

<table>
<tr><td colspan="2">Treatment with a sling (examples)</td><td>Treatment with surgery (example)</td></tr>
<tr><td>Broad arm sling
  </td><td>Collar and cuff sling
  </td><td>  </td></tr>
<tr><td colspan="2">• Commonly used in the NHS
• Known to work well
• Return to activity and sport may take longer
• May avoid the need for surgery
• May need surgery after all if the bone does not heal properly</td><td>• Commonly used in the NHS
• Known to work well
• Return to activity and sport may be quicker
• Risk of infection from surgery
• Increased risk of another break because the bone next to the metalwork is a weak point
• May need further surgery to remove the metalwork</td></tr>
</table>

Why have I been invited to take part in DIDACT?

You have been invited to take part in this study because:

- you are aged 18 years or over
- the outer part of your collarbone has broken and become separated
- your surgeon thinks that you are suitable for the study and is happy for you to have either treatment.

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2 What happens if I take part?

1. Consent

If you decide to take part in the study, we will ask you for your written consent (either on paper or electronically) and to answer a list of questions.

2. Randomisation

Taking part in this study means you and your surgeon can't choose the treatment for your broken collarbone. Instead, we will use a process called randomisation that will give you an equal chance of receiving either treatment.

Your surgeon agrees this is the fairest way to reliably compare the two treatments and find out which one is best for patients.

3. Initial sling care and then consider surgery or surgery from the start

Whether you have sling care and/or surgery, you will have physiotherapy and receive guidance for home exercises.

If you have your shoulder supported with a sling:

- You'll typically be wearing a sling for between 2 and 4 weeks.
- You can start taking off the sling once your shoulder is less painful and your bone is healing.
- Overall, you could be using a sling for up to 6 to 8 weeks.
- You will receive information to help you comfortably wear your sling.
- **In some cases, the bone doesn't heal in a sling. If your bone is still not healing, after typically around 3 months, your surgeon will discuss with you the need for surgery.**

If you have surgery:

- Your surgeon will use metalwork (such as a plate and screws) to provide stability to your broken collarbone.
- You will wear a sling usually for a few days after surgery.
- You will receive information to help you comfortably wear your sling.
- In some cases, the metalwork causes problems and a second operation is needed to remove it.

At some hospitals, patients may be treated surgically with a hook plate. Hook plates need a further operation to remove them due to the risk of damage to the group of muscles and tendons that stabilise the shoulder joint. This in turn could slow recovery and be of more pain and burden to patients. For these reasons, the patient representatives we talked with about the study discouraged their inclusion and consequently hook plates will not be used in this study.

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4. Imaging that will be used for the study

All patients with a broken collarbone have X-ray pictures and may also have X-ray 'movies' (fluoroscopy) taken to provide their doctors with information. If you take part in this study, you may need to have extra X-rays at 12 months that you would not routinely have. These X-ray procedures use ionising radiation to form images of your body and provide your doctor with other clinical information. Ionising radiation may cause cancer many years or decades after the exposure.

We are all at risk of developing cancer during our lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. Taking part in this study will add only a very small chance of this happening to you.

5. Collecting your information

To find out which treatment for broken collarbones is best for patients, we will regularly contact all 214 patients who take part in our study. This will include attending hospital when feasible for routine appointments at 6 weeks and at 3 and 12 months from taking part in the study. This will include an assessment of bone healing and whether any further treatment is necessary.

We will ask you to complete questionnaires at 6 weeks and at 3, 6 and 12 months after your decision to take part in the study. Each questionnaire will contain questions about how you are doing and should take around twenty minutes to fill in. You may complete the questionnaire:

- Electronically, or
- by post (a prepaid return envelope will be provided).

A member of your family or friend may help you fill in the questionnaires. If necessary, the study team can also help, via a telephone or video call. The telephone or video call will not be recorded.

If you agree, you will receive text messages to remind you to complete the questionnaires.

The hospital will securely send to the research team information about your shoulder problem, any treatment you have received and any related problems you have had.

With your permission, we may use either NHS Digital or Community Health Index to help contact you depending on where you live in the United Kingdom.

6. End of participation

Your participation in the study will end when you have completed the final questionnaire. Once we have collected and analysed the information from all 214 patients, we will publish the results of the study. This is to help healthcare professionals and the general public learn from the study. On completion of the study, we will send you a summary of the results.

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7. Patient videos about taking part

To help you decide to take part, there are videos you can watch at this website or scan the QR code. The videos feature patients who have experienced similar injuries and share their thoughts on joining the study.

3 Do I have to take part?

It's your choice

You do not have to take part in this study if you do not want to. Even if you decide to take part, you can change your mind at any time.

What if I don't want to take part?

If you choose not to take part in the study, your surgeon will discuss with you which treatment you prefer to have. The standard of care you receive won't be affected by your decision to take part in the study.

What if I do not want to carry on with the study?

You can leave the study at any time. You do not have to give a reason. It will not affect your hospital care or rights in any way. If you do withdraw, or lost capacity to consent during the study, we will keep all the information already collected about you.

4 What are the possible benefits of taking part?

Treating your type of collarbone injury can only be improved with the help of patients. If you decide to take part in this study, we hope it will help improve medical care for future patients and be a rewarding experience for you. You may also have more support because of the wider team involved in this research.

This study has been given a favourable opinion by an independent group of people called a Research Ethics Committee to protect your interests.

People treated for your injury or with similar injuries have commented on our plans for the study and its materials. They will continue to do this throughout the study.

5 What are the possible disadvantages and risks of taking part?

All surgery involves risks, such as from general anaesthesia, bleeding, deep vein thrombosis, damage to nerves and blood vessels in the surgical area and infection. If you are treated with a sling, you may experience swelling, bruising, discomfort or stiffness. You may also need surgery after initial sling care if the bone does not heal.

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However, there is no increased risk to you by taking part in the study. The NHS has treated patients with your type of collarbone injury for many years. You will have the same risks of surgery and/or wearing a sling as patients who do not take part in the study.

6 More information about taking part in DIDACT

What happens if there is a problem?

It is very unlikely that you would be harmed by taking part in this type of study. However, if you are concerned with any aspect of this study, you should speak to your surgeon or a researcher using the contact details provided below. They will do their best to answer your questions.

If you remain unhappy and wish to make a complaint, you should contact the Patient Advice and Liaison Services (PALS) officer at your hospital or equivalent such as the Patient Advice and Support Service (PASS).

In the event that something goes wrong from taking part in the study, and this is due to someone's negligence then you may have grounds for a legal action. You may, however, have to pay your legal costs. Then normal National Health Service complaints mechanisms will still be available to you.

Will taking part in the study cost me anything, and will I be paid?

Taking part will not cost you anything. You don't need to make any extra hospital visits. To thank you for your time, we will send you a gift voucher each time you complete a questionnaire: 6 weeks (£5), 3 months (£5), 6 months (£20) and 12 months (£20) after your decision to take part.

Will my taking part be kept confidential?

1. Contacting you during the study

Your hospital will contact you about appointments. The University of York will contact you about completing the questionnaires and send the vouchers. Your contact details will be stored securely by the University of York and your hospital. Anyone who sees your contact details and your medical records will have a duty of confidentiality.

Your name and contact details will not be passed to anyone outside of the research team. Only authorised staff will have access to these personal details.

To avoid using your personal details when collecting information for the study, we will use a unique number for you.

2. End of the study

At the end of the study, all information collected about you will be securely saved for 5 years. Then any identifiable information will be destroyed. Study results that do not include personal details about you may be stored indefinitely so that researchers can use them in the future.

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3. Keeping your information safe

University Hospitals of Leicester NHS Trust is the Sponsor of this study. This means it oversees the study to ensure information about you is used properly. It will be kept safe and secure by your hospital and University of York, who is organising the research and processing the information, in line with the General Data Protection Regulation (GDPR) and the Data Protection Act 2018.

Information about you may also be accessed by authorised individuals from the Sponsor, regulatory authorities or your hospital for monitoring and audit purposes. More details about information we will collect on you are at the end of this information sheet. You may also read about how we will use your personal data and what are your rights at these websites:

https://www.york.ac.uk/records-management/dp/your-info/privacynotice-researchparticipants/

https://www.york.ac.uk/healthsciences/research/trials/trials-gdpr/
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/

Who is organising and paying for the research?

The National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (NIHR150159) is paying University Hospitals of Leicester NHS Trust, who is the study Sponsor, and the research team to do this study. Your surgeon will not get paid for their involvement. Your hospital will be paid to cover the cost of collecting data.

7 How to contact us

If you need further information, please contact:

Principal Investigator: [Insert site-specific contact details]

Research Nurse(s): [Insert site-specific contact details]

If you would like independent advice about taking part, please contact:

Patient Advice and Liaison Service (PALS)/Patient Advice Support Service (PASS) [or, for example, R&D] on: [Insert site-specific contact details].

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8 Further details about information we will collect on you

Please read this section for further details about the information we will collect on you.

How will we use information about you?

If you take part, we will tell your GP and any doctor or health care professional who may be treating you. Your GP will also be advised of any significant information relating to your health and safety that arises while taking part in the study.

We will need to use information from you, your medical records and NHS Digital or Community Health Index (to help contact you) for this study.

This information will include your name and contact details, date of birth, sex and gender, and ethnicity. People will use this information to do the research or to check records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

How will your information be stored?

Information collected about you during the research and from your health records will be held securely at your hospital and by University of York, who are organising the research, or at an alternative secure facility. Information will be kept strictly confidential in line with the UK General Data Protection Regulations (GDPR) and Data Protection Act 2018.

Your name, address, email and telephone number (as applicable) will be stored securely at the University of York and your hospital to allow us to contact you about study. Your information will be stored on paper or on Research Electronic Data Capture (REDCap) which is a secure 'cloud' hosted server designed to collect and store research data. If you agree to share your telephone number to receive text messages about the completion of questionnaires, you will sent these using a secure UK-based text message service which has been approved by University of York.

All information about you will be kept safe and secure. The Sponsor, as data controller, has to ensure that it is in the public interest when we use personal data from people who have agreed to take part in research. This provides the legal basis for our use of your data; GDPR Article 6(1)(e) and Article 9(2) (j).

This means that when you agree to take part in a research study, we will use your data (including your health data) in the ways needed to conduct and analyse the research study. Health and care research should serve the public interest, which means that we must demonstrate that our

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research serves the interests of society as a whole. Research will be carried out in accordance with the UK Policy Framework for Health and Social Care Research.

At the end of the study, the data collected from you will be securely archived for 5 years. Confidential and secure destruction of your personal information will then be arranged.

Anonymised results from the study may be stored indefinitely for other analyses in the future. Any identifying information will be kept strictly confidential, and access will be limited to the original study team. Researchers analysing the data in the future will be unable to identify you.

Anyone who views the information collected during the study, and your medical records, will have a duty of confidentiality to you as a research participant.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your medical records. If you do not want this to happen, tell us and we will stop.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option for us to use the data saved from this study for use in future research.

Where can you find out more about how we use your information?

- www.hra.nhs.uk/information-about-patients/
- Ask one of the research team using the contact details provided.

Thank you for reading this information sheet and for thinking about taking part in this study.

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