

# DEFROST: A clinical trial testing metformin as a treatment for frozen shoulder or shoulder tendinopathy.

ACTRN12616000629437

---

<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 2, Phase 3
<b>Sponsor</b>	Northern Sydney Local Health District - Professor David Sonnabend and Professor Lyn March
<b>Enrollment</b>	400 participants

## Plain Language Summary

---

This trial is testing whether a drug called metformin — currently used to treat type 2 diabetes — can also treat frozen shoulder and shoulder tendinopathy (tendon pain). Researchers at Royal North Shore Hospital believe metformin may target the root cause of stiffness and pain in these shoulder conditions. Half of the participants will receive metformin, and half will receive a placebo (a look-alike pill with no active ingredient). Neither the patient nor the doctor will know which one is being taken. The study involves 4 visits over 3 months.

You may be eligible if:

- You are between 40 and 70 years old
- You have pain and stiffness in one shoulder only
- Your shoulder pain has been present for less than 6 months
- You do not have diabetes or pre-diabetes
- Your shoulder X-ray is normal
- You are willing to attend 4 appointments at Royal North Shore Hospital

You may NOT be eligible if:

- You have diabetes, pre-diabetes, or impaired glucose tolerance
- You have had previous shoulder surgery, steroid injections, or manipulation under anaesthesia
- You have a torn rotator cuff on ultrasound or MRI
- You have serious heart, kidney, or vascular problems
- You are pregnant, breastfeeding, or could become pregnant
- You have taken oral steroids in the last 3 months
- You are currently taking fluoroquinolone antibiotics (e.g. ciprofloxacin)

Talk to your doctor about whether this trial might be right for you.

## Key Eligibility Criteria

---

### Inclusion (17)

- Patients aged between 40 and 70;
- Patients with unilateral shoulder pain (spontaneous or following minor trauma);
- Patients with pain at end of shoulder range of movement (ROM) in all directions with pain on the visual analogue scale (VAS) of greater than 4 out of 10;
- Patients with loss of glenohumeral ROM in at least 2 of 3 planes (flexion, abduction, extension);
- Patients with loss of greater than 20 per cent or 30 degrees external rotation in adduction compared with asymptomatic side;
- ... and 12 more (see full listing online)

### Exclusion (18)

- Patients with a rotator cuff disruption on ultrasound or MRI (ie full thickness or partial thickness cuff tear);
- <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12616000629437>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [anzctr.org.au](http://anzctr.org.au). Generated by [ClinicalTrialsFinder.org](http://ClinicalTrialsFinder.org).

- Patients who have a known abnormality in glucose tolerance including impaired glucose tolerance, impaired fasting glucose, type 1 or type 2 diabetes mellitus;
  - Patients with impaired renal function (estimated glomerular filtration rate (eGFR) less than 45mL per minute);
  - Patients who have symptoms of frozen shoulder which have been present for more than 6 months;
  - Patients who have had previous shoulder surgery, hydrodilatation or manipulation under anaesthesia procedure;
- ... and 13 more (see full listing online)

## Locations (1 total)

---

Royal North Shore Hospital - St Leonards, NSW, Australia