

A randomised prospective study of analgesic protocols for the management of orthodontic pain in relation to fitting of fixed appliances

ACTRN12612000541808

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| Status | RECRUITING |
| Phase | Phase 4 |
| Sponsor | The University of Queensland |
| Enrollment | 185 participants |

Plain Language Summary

This study is looking at whether taking pain medication before and after getting braces fitted can reduce the discomfort that commonly occurs in the first 48 hours of orthodontic treatment. Participants will be randomly assigned to take either ibuprofen, paracetamol (acetaminophen), or a placebo (inactive pill) starting one hour before the braces are fitted. Pain levels will be recorded at several time points over the first week of treatment.

You may be eligible if:

- You are between 14 and 19 years old
- You are about to start full fixed orthodontic treatment (braces) for the first time
- You have not had a dental extraction in the past two weeks
- You are willing to follow a strict pain medication schedule and complete pain rating forms

You may NOT be eligible if:

- You need to take preventive antibiotics before dental procedures
- You have a systemic disease
- You are pregnant
- You have a reason you cannot take anti-inflammatory medications (NSAIDs)

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

Key Eligibility Criteria

Inclusion (19)

- It is anticipated at least 185 subjects will be recruited. Consecutive patients who meet the following criteria will be recruited:
- subject to be between the ages of 14 and 19 years old at the commencement of treatment
- subject agrees, with consent of parent/guardian, to complete a 100mm VAS at predetermined intervals within the first week of full fixed orthodontic therapy as follows:
 - T1: 2 hours after fitting of braces
 - T2: 6 hours after fitting of braces
- ... and 14 more (see full listing online)

Exclusion (4)

- subject does not require prophylactic antibiotic coverage
- subject has no systemic diseases
- subject cannot be pregnant
- subject has no contraindication to the use of NSAID

Locations (1 total)

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12612000541808>

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