

# STARFAST: Study of Traumatic Brain Injury (TBI)/ Concussions in Australian-Rules Footballers receiving AST-004.

ACTRN12625000657426

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Status	RECRUITING
Phase	Phase 2
Sponsor	Astrocyte Pharmaceuticals Pty Ltd
Enrollment	60 participants

## Plain Language Summary

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Concussion in contact sport is a serious and common injury, and current management is largely focused on rest and gradual return to play. This study is testing a new drug called AST-004 as an immediate treatment given to AFL footballers within six hours of sustaining a concussion during a match. The treatment is delivered as an intravenous infusion (a drip), and researchers will track whether it reduces blood markers of brain injury, speeds up clinical recovery, and is safe.

The study also includes neuropsychological testing — memory and cognitive assessments — to measure whether brain function recovers more quickly with the treatment.

This study is open to AFL players aged 18 and over who have been diagnosed with a concussion during a match by a registered medical practitioner and can receive treatment within six hours. Players who have had a concussion in the past six months, have a history of seizures, kidney disease, or migraine requiring prescription medication are not eligible.

## Key Eligibility Criteria

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### Inclusion (12)

- Male or female subject at least 18 years of age
- Subject can provide Informed Consent
- Concussion occurring in the course of AFL match play and
- diagnosed by a registered medical practitioner
- Able to initiate infusion of AST-004 within 6 h of concussion
- ... and 7 more (see full listing online)

### Exclusion (28)

- Participating in an interventional clinical study that may
- affect the results of this study (an observational study
- acceptable)
- Subject has had a documented concussion in the previous 6
- months
- ... and 23 more (see full listing online)

## Locations (1 total)

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SA, Australia

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<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12625000657426>

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