

Injection therapy to muscle injuries in professional football players

Submission date 16/07/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 27/08/2009	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 17/04/2025	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1.0.5

Study information

Scientific Title
A pilot study on intramuscular injection therapy of Actovegin® in elite football players with muscular injuries

Acronym

ActoFC

Study objectives

Actovegin® injection therapy can reduce number of days from muscle injury for the player to return to training with the first team.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cardiff University Ethics Board with independent review approved on the 02/07/2009. NHS Ethics and MHRA approval pending as of 17/07/2009.

Study design

Randomised double-blinded single-centre interventional trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Grade 1 and Grade 2 muscle injury

Interventions

3 x intra-muscular injection of normal saline or Actovegin® with Traumeel® directly to the injury site, 1 ml injected 1 cm above the injury site and 1 ml injected to 1 cm below the injury site.

Duration of treatment will be 1 week, duration of follow up will be determined by recovery time and when they are back playing with the first team.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Actovegin®

Primary outcome(s)

Number of days from injury for the player to return to training with the first team

Key secondary outcome(s)

1. Player's perception of pain and effectiveness of treatment
2. Player's isokinetic and isometric data

Completion date

31/07/2012

Reason abandoned (if study stopped)

Not started

Eligibility

Key inclusion criteria

1. Informed consent
2. Aged greater than 18 years, male only
3. Clinical and magnetic resonance imaging (MRI) diagnosis of muscle injuries
4. Grade 1 or 2 muscle tear
5. No previous allergic reaction to Actovegin®

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Male

Key exclusion criteria

1. Grade 3 or more muscle injuries
2. Fractures
3. Other soft tissue injuries besides muscle tears

Date of first enrolment

01/03/2010

Date of final enrolment

31/07/2012

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre

Cardiff University
Cardiff
United Kingdom
CF24 3AA

Sponsor information

Organisation
Cardiff University (UK) - Medical Engineering

ROR
<https://ror.org/03kk7td41>

Funder(s)

Funder type
University/education

Funder Name
Cardiff University (UK) - Medical Engineering

Funder Name
Cardiff City Football Club (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration