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Injection therapy to muscle injuries in professional football players

Submission date	Recruitment status	[X] Prospectively registered
16/07/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/08/2009	Stopped	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
17/04/2025	Injury, Occupational Diseases, Poisoning	[_] 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