

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-14 End Date:2016-04-15

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0010	Subject Initials :Y-H	DOB :10/18/1985	Sex:Female	Race:Asian	Height:153cm	Weight:47.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/11/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/29/2015	06/02/2015		Related	Moderate	
Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity	
Concomitant medication**(Othervalue:)	Not applicable	Led to study termination	Resolved			
Event Description: Moderate OHSS patients, improved canceled after embryo transfer.						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition	Start Date	Related to study condition	Ongoing			

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NA/EMR700623-541/C02-0010

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-14 End Date:2016-04-15

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0011	Subject Initials :P-X	DOB :12/07/1994	Sex:Female	Race:Asian	Height:160cm	Weight:60.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/11/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/27/2015	06/03/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Not applicable	Led to study termination	Resolved		
Event Description: Moderate OHSS occurs canceled embryo transfer, OHSS improvement						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition				Start Date	Related to study condition	Ongoing
ectopic pregnancy Salping ectomy				Uk-Unk-2013	On treatment/medication	

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