Non Serious Adverse Drug Reactions Report

Start Date:2016-04-08 End Date:2016-04-11

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0202	Subject Initials :F-Q	DOB :06/09/1985	Sex:Female	Race:Asian	Height:159cm	Weight:65.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	08/27/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	09/11/2015	09/16/2015		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:

Subject received concomitant medications:

Does the subject have any relevant past or present medical conditions:Yes

Condition	Start Date	Related to study condition	Ongoing
HSG: bilateral tubal patency	Uk-Unk-2013	Not on treatment/medication	
Laparoscopic surgery: pelvic adhesions dissection, bilateral mesosalpinx cystectomy	Uk-Unk-2014	Not on treatment/medication	
Tubal examination: smooth	Uk-Unk-2014	Not on treatment/medication	

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Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0206	Subject Initials :YPZ	DOB :10/20/1980	Sex:Female	Race:Asian	Height:150cm	Weight:47.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	08/28/2015		187.5			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	09/14/2015	09/18/2015		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:

Subject received concomitant medications:

Does the subject have any relevant past or present medical conditions:Yes

Condition	Start Date	Related to study condition	Ongoing
HSG: bilateral tubal occlusion	Uk-Unk-2011	Not on treatment/medication	
Laparoscopy surgery: pelvic adhesions dissection, bilateral tubal surgery to clear.	Uk-Unk-2011	Not on treatment/medication	
HSG: bilateral tubal occlusion	Uk-Unk-2013	Not on treatment/medication	
Laparoscopy surgery: pelvic adhesions dissection, uterine fibroids dug surgery, tubal surgery to clear, coherent liquid skill.	Uk-Unk-2013	Not on treatment/medication	

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Start Date:2016-04-08 End Date:2016-04-11

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0207	Subject Initials :JHZ	DOB :09/03/2015	Sex:Female	Race:Asian	Height:160cm	Weight:55.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	08/28/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	09/13/2015	09/18/2015		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:

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 laparoscopic surgery: Left salpingectomy	Uk-Unk-2011	Not on treatment/medication	
Ectopic pregnancy laparoscopic surgery: Right salpingectomy	Uk-Unk-2013	Not on treatment/medication	
HSG: bilateral tubal occlusion	Uk-Unk-2014	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-04-08 End Date:2016-04-11

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0208	Subject Initials :MQW	DOB :09/24/1988	Sex:Female	Race:Asian	Height:156cm	Weight:54.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	08/28/2015		150			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	09/14/2015	09/18/2015		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:						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:Yes						
Condition				Start Date	Related to study condition	Ongoing
Hysteroscopic resection of endometrial polyps				Uk-Unk-2015	Not on treatment/medication	