Non Serious Adverse Drug Reactions Report

Start Date:2016-05-17 End Date:2016-05-18

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0043	Subject Initials :F-H	DOB :03/13/1983	Sex:Female	Race:Asian	Height:164cm	Weight:54.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/13/2015	225	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	05/30/2015	06/05/2015		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 patients, improved canceled after embryo transfer.

Subject received concomitant medications:

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

Condition	Start Date	Related to study condition	Ongoing
Laparoscopic tubal ectopic pregnancy at the right side of the window to take embryo	Uk-Unk-2005	Not on treatment/medication	
Under the right fallopian tube ectopic pregnancy laparoscopic surgery	Uk-Unk-2007	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-17 End Date:2016-05-18

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0178	Subject Initials :XSC	DOB :10/11/1988	Sex:Female	Race:Asian	Height:155cm	Weight:54.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/27/2015	200	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	06/10/2015	06/16/2015		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:Moderate OHSS patients, improved canceled after embryo transfer.

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 resistance.	Uk-Jan-2013	Not on treatment/medication	
Laparoscopy surgery: pelvic adhesions dissection, bilateral salpingo-repair plastic surgery, normal uterine shape.	Uk-Jan-2013	Not on treatment/medication	
Hysteroscopy normal, water surgery: incomplete right fallopian tube obstruction	Uk-Feb-2015	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-17 End Date:2016-05-18

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0179	Subject Initials :HYZ	DOB :05/14/1991	Sex:Female	Race:Asian	Height:158cm	Weight:53.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/27/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	06/11/2015	06/16/2015		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: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 laparotomy: the left fallopian tube removal.	Uk-Unk-2009	Not on treatment/medication	
Abdominal ectopic pregnancy conservative surgery.	Uk-Unk-2010	Not on treatment/medication	
Hysteroscopy: endometrial polyp excision.	Uk-Jan-2015	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-17 End Date:2016-05-18

Study :EMR700623-541	Investigator :NA		Country of Investigator :Korea	SiteNo:K01		
Subject No :k01-0059	Subject Initials :LKH	DOB :08/05/1981	Sex:Female	Race:Asian	Height:153cm	Weight:74g
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	06/02/2015		225			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/13/2015	07/02/2015		Related	Mild	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Dose not changed	None	Resolved		
Event Description:						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition				Start Date	Related to study condition	Ongoing

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-17 End Date:2016-05-18

Study :EMR700623-541	Investigator :NA		Country of Investigator :Korea	SiteNo:K01		
Subject No :k01-036	Subject Initials :JSY	DOB :07/28/1981	Sex:Female	Race:Asian	Height:162cm	Weight:54g
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	03/13/2015		225			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	03/24/2015	04/07/2015		Related	Moderate	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Dose not changed	None	Resolved		
Event Description:						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition				Start Date	Related to study condition	Ongoing

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-17 End Date:2016-05-18

Study :EMR700623-541	Investigator :NA		Country of Investigator :Korea	SiteNo:K01		
Subject No :k01-040	Subject Initials :LBH	DOB :03/05/1985	Sex:Female	Race:Asian	Height:164cm	Weight:61g
First administration date of batch :			Batch number :			
Study Drug	Start Date		Dose	Change in Dose		
Gonal-f New Pen Stimulation Treatment	04/06/2015		225			
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	04/15/2015	04/30/2015		Related	Mild	
Causality Factors		Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)		Dose not changed	None	Resolved		
Event Description:						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition				Start Date	Related to study condition	Ongoing

Non Serious Adverse Drug Reactions Report

Start Date:2016-05-17 End Date:2016-05-18

Study :EMR700623-541	Investigator :NA		Country of Investigator :Korea	SiteNo:K01		
Subject No :k01-050	Subject Initials :KHG	DOB :04/22/1984	Sex:Female	Race:Asian	Height:150cm	Weight:46g
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/03/2015	300	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	05/14/2015	05/29/2015		Related	Mild

Causality Factors	Action Taken with Study Treatment	Other action taken	Outcome	AE Special Interest	AE dose limiting toxicity
None(Othervalue:)	Dose not changed	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
ovary cystectomy	UK-Jan-2014	Not on treatment/medication	