Non Serious Adverse Drug Reactions Report

Start Date:2016-08-16 End Date:2016-08-17

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
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:No						
Condition				Start Date	Related to study condition	Ongoing

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-16 End Date:2016-08-17

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0087	Subject Initials :XPT	DOB :06/15/1988	Sex:Female	Race:Asian	Height:158cm	Weight:57.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment			

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/02/2015	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
Hysteroscopy normal	Uk-Mar-2015	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-16 End Date:2016-08-17

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0102	Subject Initials :HYD	DOB :10/14/1985	Sex:Female	Race:Asian	Height:163cm	Weight:57.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/19/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	06/04/2015	06/12/2015		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
Palace laparoscopy	Uk-Unk-2013	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-16 End Date:2016-08-17

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0136	Subject Initials :Q-L	DOB :03/28/1984	Sex:Female	Race:Asian	Height:154cm	Weight:47.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/22/2015	200	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	06/08/2015	06/12/2015		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 obstruction incomplete	Uk-Unk-2014	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-16 End Date:2016-08-17

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0137	Subject Initials :YLF	DOB :11/01/1989	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	05/22/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/09/2015	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
HSG: bilateral tubal obstruction	Uk-Unk-2014	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-16 End Date:2016-08-17

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0157	Subject Initials :Y-Z	DOB :07/22/1984	Sex:Female	Race:Asian	Height:156cm	Weight:55.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/25/2015	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 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
HSG: bilateral tubal obstruction	Uk-Unk-2006	Not on treatment/medication	
Laparoscopic Surgery: Tubal clear.	Uk-Unk-2007	Not on treatment/medication	
Ectopic pregnancy laparoscopic surgery: tubal embryo window.	Uk-Jan-2014	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-16 End Date:2016-08-17

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0164	Subject Initials :AHC	DOB :12/12/1982	Sex:Female	Race:Asian	Height:156cm	Weight:49.0kg
First administration date of batch :			Batch number :			

Study Drug	Start Date	Dose	Change in Dose
Gonal-f New Pen Stimulation Treatment	05/26/2015	150	

Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity
OHSS	06/12/2015	06/20/2015		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
HSG: bilateral tubal occlusion side	Uk-Unk-2012	Not on treatment/medication	
Laparoscopy Surgery: salpingostomy, pelvic adhesions dissection.	Uk-Unk-2012	Not on treatment/medication	

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-16 End Date:2016-08-17

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:2016-08-16 End Date:2016-08-17

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	Concomitant medication **	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