

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-01 End Date:2016-08-02

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0028	Subject Initials :XHL	DOB :04/12/1981	Sex:Female	Race:Asian	Height:158cm	Weight:65.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/12/2015	225				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/28/2015	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 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			
Left abdominal ectopic pregnancy salpingectomy	Uk-Unk-2002	Not on treatment/medication				
Right next laparoscopic tubal ectopic pregnancy surgery	Uk-Unk-2010	Not on treatment/medication				
Conservative treatment of ectopic pregnancy	Uk-Unk-2004	Not on treatment/medication				
Conservative treatment of ectopic pregnancy	Uk-Unk-2005	Not on treatment/medication				

01-AUG-16

NA/EMR700623-541/C02-0028

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-01 End Date:2016-08-02

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0045	Subject Initials :H-T	DOB :09/08/1983	Sex:Female	Race:Asian	Height:158cm	Weight:57.5kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/13/2015	250				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/31/2015	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 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
Hysteroscopic polypectomy				Uk-Aug-2014	Not on treatment/medication	

01-AUG-16

NA/EMR700623-541/C02-0045

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-01 End Date:2016-08-02

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0060	Subject Initials :Y-W	DOB :11/10/1981	Sex:Female	Race:Asian	Height:150cm	Weight:45.5kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/14/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/30/2015	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 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 pelvic sticking points, ovarian drilling, tubal surgery to clear.				Uk-Unk-2014	Not on treatment/medication	

01-AUG-16

NA/EMR700623-541/C02-0060

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-01 End Date:2016-08-02

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0061	Subject Initials :T-D	DOB :02/15/1988	Sex:Female	Race:Asian	Height:161cm	Weight:60.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/14/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/31/2015	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 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
salpingemphraxis,laparoscopic operation				Uk-Unk-2014	Not on treatment/medication	

01-AUG-16

NA/EMR700623-541/C02-0061

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-01 End Date:2016-08-02

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0063	Subject Initials :HMC	DOB :07/25/1981	Sex:Female	Race:Asian	Height:162cm	Weight:50.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/15/2015	250				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/01/2015	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 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
Hysteroscopic surgery through liquid				Uk-Unk-2014	Not on treatment/medication	

01-AUG-16

NA/EMR700623-541/C02-0063

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-01 End Date:2016-08-02

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0076	Subject Initials :F-L	DOB :05/15/1987	Sex:Female	Race:Asian	Height:150cm	Weight:51.5kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/15/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	05/30/2015	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 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
Sticky points lower pelvic laparoscopy surgery, tubal surgery.				Uk-Unk-2012	Not on treatment/medication	
Hysteroscopic tubal surgery				Uk-Sep-2014	Not on treatment/medication	

01-AUG-16

NA/EMR700623-541/C02-0076

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-01 End Date:2016-08-02

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0082	Subject Initials :Y-L	DOB :09/04/1986	Sex:Female	Race:Asian	Height:162cm Weight:59.0kg	
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/18/2015	150				
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 occurs canceled embryo transfer, OHSS improvement						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition			Start Date	Related to study condition	Ongoing	

01-AUG-16

NA/EMR700623-541/C02-0082

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-01 End Date:2016-08-02

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0083	Subject Initials :Y-L	DOB :08/20/1988	Sex:Female	Race:Asian	Height:158cm	Weight:54.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/18/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/03/2015	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 pelvic sticky points left salpingostomy				Uk-Unk-2013	Not on treatment/medication	

01-AUG-16

NA/EMR700623-541/C02-0083

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-01 End Date:2016-08-02

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0086	Subject Initials :YZZ	DOB :07/07/1987	Sex:Female	Race:Asian	Height:150cm	Weight:55.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/18/2015	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 occurs canceled embryo transfer, OHSS improvement						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition				Start Date	Related to study condition	Ongoing

01-AUG-16

NA/EMR700623-541/C02-0086

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-01 End Date:2016-08-02

Study :EMR700623-541	Investigator :NA		Country of Investigator :China	SiteNo:C02		
Subject No :C02-0088	Subject Initials :HLK	DOB :06/14/1986	Sex:Female	Race:Asian	Height:159cm	Weight:59.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/18/2015	150				
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 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
Palace laparoscopic pelvic surgery sticky points, bilateral tubal plastic surgery, endometriosis lesions fulguration.				Uk-Unk-2012	Not on treatment/medication	

01-AUG-16

NA/EMR700623-541/C02-0088

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-01 End Date:2016-08-02

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0089	Subject Initials :XYZ	DOB :06/12/1986	Sex:Female	Race:Asian	Height:152cm	Weight:48.5kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/18/2015	187.5				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/07/2015	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
Sticky points pelvic laparoscopy surgery, tubal surgery to clear				Uk-Nov-2012	Not on treatment/medication	

01-AUG-16

NA/EMR700623-541/C02-0089

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-01 End Date:2016-08-02

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0095	Subject Initials :MLG	DOB :08/19/1990	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	05/19/2015	150				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/03/2015	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 occurs canceled embryo transfer, OHSS improvement						
Subject received concomitant medications:						
Does the subject have any relevant past or present medical conditions:No						
Condition				Start Date	Related to study condition	Ongoing

01-AUG-16

NA/EMR700623-541/C02-0095

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-01 End Date:2016-08-02

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	

01-AUG-16

NA/EMR700623-541/C02-0102

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-01 End Date:2016-08-02

Study :EMR700623-541	Investigator :NA	Country of Investigator :China	SiteNo:C02			
Subject No :C02-0111	Subject Initials :CXW	DOB :10/10/1979	Sex:Female	Race:Asian	Height:162cm	Weight:68.0kg
First administration date of batch :			Batch number :			
Study Drug	Start Date	Dose	Change in Dose			
Gonal-f New Pen Stimulation Treatment	05/20/2015	200				
Adverse Event	Start Date	End Date	Time related to study treatment	Causality to study drug	Severity	
OHSS	06/05/2015	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
Ectopic pregnancy laparoscopic surgery, the left fallopian tube embryo window.				Uk-Unk-2012	Not on treatment/medication	
Tubal lipiodol angiography				Uk-Unk-2013	Not on treatment/medication	

01-AUG-16

NA/EMR700623-541/C02-0111

Non Serious Adverse Drug Reactions Report

Start Date:2016-08-01 End Date:2016-08-02

Study :EMR700623-541		Investigator :NA		Country of Investigator :China		SiteNo:C02		
Subject No :C02-0115		Subject Initials :KJT		DOB :07/02/1988		Sex:Female		
				Race:Asian		Height:163cm		
				Weight:52.0kg				
First administration date of batch :				Batch number :				
Study Drug		Start Date		Dose		Change in Dose		
Gonal-f New Pen Stimulation Treatment		05/21/2015		150				
Adverse Event		Start Date		End Date		Time related to study treatment		
OHSS		06/05/2015		06/12/2015		Causality to study drug		
						Severity		
						Related		
						Moderate		
Causality Factors			Action Taken with Study Treatment		Other action taken		Outcome	
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		
HSG examination: bilateral tubal occlusion				Uk-Unk-2012		Ongoing		
Laparoscopy surgery: pelvic sticky points, bilateral tubal ostomy + right side mesosalpinx cyst removal.				Uk-May-2015		Not on treatment/medication		

01-AUG-16

NA/EMR700623-541/C02-0115

